UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA
Case Number 15-cv-2210 PJS/BT

RONALDO LIGONS,
BARRY MICHAELSON,
JOHN ROE, and JANE ROE,
JOHN MILES AND JANE MILES,
JOHN STILES AND JANE STILES,
individually, and on behalf of those
similarly situated,
Plaintiffs,
v.
MINNESOTA DEPARTMENT OF CORRECTIONS,
THOMAS ROY,
Minnesota Commissioner of Corrections,
in his official capacity,
DR. DAVID A. PAULSON, M.D.,
in his individual and his official capacities
for actions under color of law as Medical
Director, Minnesota Department of
Corrections,
NANETTE LARSON,
in her individual and her official capacities
for actions under color of law as Health
Services Director, Minnesota Department of
Corrections,
DR. D. QUIRAM, M.D.,
in his individual and his official capacities
for actions under color of law as Plaintiffs'
treating physician at Minnesota Correctional
Facility, Stillwater,
DR. R. HANSON, M.D.,
in his individual and his official capacities
for actions under color of law as Plaintiffs'
treating physician at Minnesota Correctional
Facility, Stillwater,

Exhibits Only

JOHN and JANE DOES A-J,
in their respective individual and official capacities for actions under color of law as staff of Minnesota Correctional Facilities, Stillwater and Faribault,
and
CENTURION OF MINNESOTA, L.L.C.,
Defendants.

DEPOSITION OF:
NANETTE LARSON

Taken on 3/11/16 By Charles G. Williamson

MINNESOTA DEPARTMENT OF CORRECTIONS

Professional and Technical Services Contract

State of Minnesota

SWIFT Contract No.: 70449

This Contract is between the State of Minnesota, acting through its Commissioner of the Department of Corrections ("State" or "DOC") and Centurion of Minnesota, LLC, whose designated mailing address is 7700 Forsyth Blvd., St. Louis, MO 63105 ("CONTRACTOR").

Recitals

1. Under Minn. Stat. § 15.061 the State is empowered to engage such assistance as deemed necessary.
2. The Minnesota Department of Corrections (DOC) is in need of health care services for the inmate population.
3. The CONTRACTOR represents that it is duly qualified and agrees to perform all services described in this Contract to the satisfaction of the State.

Contract

1. Term of Contract

1.1 Effective date: October 15, 2013, or the date the State obtains all required signatures under Minn. Stat. § 16C.05, subd. 2, whichever is later ("Effective Date"). The CONTRACTOR must not begin work under this Contract until this Contract is fully executed and the CONTRACTOR has been notified by the State's Authorized Representative to begin the work.

1.2 Performance start date: January 1, 2014.

1.3 Expiration date: June 30, 2016, or until all obligations have been satisfactorily fulfilled, whichever occurs first. This Contract, upon mutual agreement of the parties, may be amended in increments approved by the State, for a total duration not to exceed five years.

1.4 Survival of terms: The following clauses survive the expiration or cancellation of this Contract: 9. Indemnification; 10. State audits; 11. Government data practices and intellectual property; 14. Publicity and endorsement; 16. Governing law, jurisdiction, and venue; and 17. Data disclosure.

2. Definitions

2.1 Inmates/Offenders

Includes only those persons enumerated in the Daily Adult Facility Offender Population Report and highlighted in Attachment 5, as attached and incorporated into this Contract, plus juvenile males at Red Wing and furloughed Red Wing juveniles. These numbers shall include Minnesota inmates housed in county facilities on legal writs and in other State and Federal correctional facilities under exchange programs. The eligibility feed sent to the CONTRACTOR by the DOC does not determine the official daily inmate count.

All inmates as described in the foregoing shall receive the services described in this Contract. Inmates from other states residing in DOC correctional facilities under the Interstate Compact Contract shall receive all On-Site Care, including prescription drugs. CONTRACTOR is not responsible for Off-Site Care costs of inmates from other states residing in Minnesota under the Interstate Compact Contract.

2.2 Facilities

The DOC facilities ("Facility" or "Facilities") covered under this Contract are noted in Attachment 4, which is attached to and incorporated into this Contract.

2.3 Claims Expenses

For the purposes of this Contract, the following services will be considered claims expenses ("Claims Expenses") and will be paid from the Risk Pool, including but not limited to:

a) Inpatient hospitalization and related physician fees
b) Outpatient surgeries/procedures

EXHIBIT #1 (3-11-16) CW

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c) Emergency room services
d) Laboratory services
e) Radiology services, including over-read
f) Contracted dialysis services, including required medications
g) Specialty physician services provided on-site or off-site (not included in staffing plan)
h) Ambulance and other medical transportation services
i) Long-term facility and hospice care
j) Offsite oral surgeon services deemed to be medical in nature
k) Medical Supplies
l) All prosthetic devices, glasses, hearing aids, and orthopedic braces
m) Pharmaceuticals (including Hep C medications)
n) Vision care services
o) Oncology services including radiation and chemotherapy treatments
p) Bone marrow and solid organ transplant
q) Infusion services (if nursing provided from staffing fund).

Additions to this may be made upon mutual agreement of both parties.

2.4 On-Site Care
For the purposes of this Contract, on-site care ("On-Site Care") is defined as medical services which the Contractor provides at the Facilities. On-Site Care is further detailed in Attachment 1.

2.5 Off-Site Care
For the purposes of this Contract, off-site care ("Off-Site Care") is defined as medical services which the CONTRACTOR does not provide at the Facilities and which are provided to the Inmate outside of DOC Facilities.

2.6 Risk Pool
For the purposes of this Contract, risk pool ("Risk Pool") is defined as funds used to pay for Claims Expenses, as defined in Section 2.3, excluding any such funds paid by Medicaid. Savings or amounts paid in excess of the Risk Pool will be shared as specified in Section 5.

2.7 Subcontractor
For the purposes of this Contract, a subcontractor ("Subcontractor") includes a person or company that CONTRACTOR contracts with to perform services required under this Contract but specifically does not include the following: network providers; hospitals and physician groups; specialty, diagnostic and interventional care providers; supply vendors; pharmacy vendors; and medical equipment vendors.

3. Duties

3.1 CONTRACTOR's duties:

3.1.1 The CONTRACTOR, who is not a DOC employee, will provide medical and psychiatric services to all Inmates, male and female, adult and juvenile, residing in Facilities or committed to the care and custody of the DOC and will provide health care contract management services for the DOC. The CONTRACTOR will provide all services in compliance with all applicable federal and state standards, statutes, and regulations, including, but not limited to, the standards of the ACA, the Minnesota Department of Health, the regulations of all Minnesota health care professional credentialing boards and commissions, and all regulations and policies of the Department of Corrections; including the Health Services policies of the DOC. The CONTRACTOR will also provide services in compliance with the request for proposal response it submitted to the DOC on June 13, 2013 ("Response") and July 29, 2013.

3.1.2 The CONTRACTOR shall be primarily responsible for making all decisions with respect to the type, timing, and level of services needed by Inmates covered by the Contract, including, without limitation, the determination of whether an Inmate is in need of clinic care, hospitalization, referral to an outside specialist, or otherwise in need of specialized care. However, the DOC retains oversight and ultimate responsibility for the health care services provided to Inmates. If necessary, the DOC can and will override clinical decisions made by the CONTRACTOR's health care professionals to ensure the best possible outcome within the DOC's budgeting restraints and to meet legal requirements. Except as herein otherwise provided, the CONTRACTOR shall be the primary supplier and/or coordinator (responsible for scheduling of On-Site and Off-site Care) of all medical and psychiatric consulting services,

and as such shall have joint responsibility with the DOC for the implementation, modification, and continuation of any and all health care programs for inmates. Specific services are further set forth herein and in Attachment 1 (On-Site Services), Attachment 2 (Administrative Services), Attachment 3 (Site Staffing Matrix), and Attachment 4 (Facilities Covered as Part of this Agreement), all of which are attached and incorporated into this Contract.

3.2 **Transition Plan:** CONTRACTOR shall provide the State with a transition plan, moving the DOC from its incumbent vendor to CONTRACTOR, no later than 30 calendar days after the Contract Effective Date. The transition plan shall include items similar to those set forth in the sample transition plan contained in CONTRACTOR's Response, a copy of which is attached hereto and labeled Attachment 6. Upon expiration of this Contract, CONTRACTOR will work in good-faith with DOC, participate in meetings, and take all reasonable steps necessary to transition to any subsequent provider, if applicable.

3.3 **State duties:** The DOC will retain responsibility for: 1) all state employees at the Facilities and will provide security for its inmates; 2) all medical equipment purchased by the DOC; 3) the physical plant needs of each Facility; and 3) security coverage at all Facilities, hospitals, physicians' offices, and any other location in which inmate medical services are provided hereunder.

4. **Time**

The CONTRACTOR must comply with all the time requirements described in this Contract. In the performance of this Contract, time is of the essence.

5. **Consideration and payment**

5.1 **Consideration.** The State will pay for all services performed by the CONTRACTOR under this Contract as follows:

5.1.1 **January 1, 2014 – June 30, 2014**

a) The DOC will pay a base amount ("Base Amount") of $13,049,157 for the first contract term, defined as January 1, 2014 through and including June 30, 2014, subject to the conditions and exclusions as described in clauses 2, 5.2 and 5.3. The DOC will pay the staffing funds and administrative expenses on a twice-monthly basis based on invoices sent by the CONTRACTOR. CONTRACTOR will use the first term Base Amount fees in the following ways: fees for staffing expenses will be $2,052,246 (the "Staffing Funds"); Claims Expenses $8,678,574; and $2,318,337 for CONTRACTOR administrative expenses ("Administrative Expenses"). The Base Amount assumes an inmate population of 9000 or fewer. If the inmate population exceeds 9000, additional payments will be due to the CONTRACTOR as specified in 5.1.1(f) below.

b) Claims Expenses that vary from the amount of $8,678,574 will be settled as specified in clauses 2.6 and 5.1.1(e) .The Base Amount of Administrative Fees (plus additional compensation) is to be used by the CONTRACTOR to cover its expenses in delivering medical services to inmates under this Contract.

c) Any financial liquidated damages imposed pursuant to this Contract will be paid directly from Administrative Expenses. This payment adjustment will occur monthly or as otherwise agreed to in writing by the DOC and the CONTRACTOR.

d) The DOC will retain all Staffing Funds not used in each term of the Contract. Credits will be made by the CONTRACTOR to DOC on the twice-monthly invoices after the amount and timing of the credit is mutually agreed upon by both parties.

e) The Risk Pool attachment point is $8,678,574 based on 9000 or fewer inmates. The DOC and CONTRACTOR will share equally Claims Expenses over $8,678,574.

The DOC will receive 75% of any savings for Claims Expenses below $8,678,574.

If the number of inmates exceeds 9000, the Risk Pool attachment point will be increased by the total amount of the additional Claim Expenses component remitted by the DOC to the CONTRACTOR as specified in 5.1.1(f).

f) Additional compensation: For population levels above 9000, the CONTRACTOR will receive a per diem expense of $6.70 per inmate exceeding 9000. Of this amount,

d) The DOC will retain all Staffing Funds not used in the third term of the Contract. Credits will be made by the CONTRACTOR to DOC on the twice-monthly invoices after the amount and timing of the credit is mutually agreed upon by both parties.

e) The Risk Pool attachment point is $18,172,092 based on 9000 or fewer inmates. The DOC and CONTRACTOR will share equally Claims Expenses over $18,172,092.

The DOC will receive 75% of any savings for Claims Expenses below $18,172,092.

If the number of inmates exceeds 9000, the Risk Pool attachment point will be increased by the total amount of the additional Claim Expense component remitted by the DOC to the CONTRACTOR as specified in 5.1.3(f).

f) Additional compensation: For population levels above 9000, the CONTRACTOR will receive a per diem expense of $7.01 per inmate exceeding 9000. Of this amount, $5.53 is for Claims Expenses, and $1.48 is for the CONTRACTOR's Administrative Expenses.

5.2 **Risk Pool Attachment Point**

5.2.1 As set forth in the RFP and CONTRACTOR's Response, the intent of the Risk Pool is for the parties to share in either the cost of Claims Expenses exceeding the Risk Pool attachment point for each Contract term or the savings if the cost of Claims Expenses is less than the Risk Pool attachment point for each Contract term.

5.2.2 As the number of inmates covered by third-party health insurance, either public or private, is not known at this time, the parties intend to revisit the Risk Pool attachment point and credits for claims within six months of the Contract Performance Start Date.

5.2.3 CONTRACTOR shall invoice DOC for the costs associated with the Risk Pool at least one time per Contract term and more often if requested by DOC. DOC shall retain and manage Risk Pool funds subject to the terms herein.

5.2.4 Claims Expenses will be reconciled at the end of each Contract term using the modified Risk Pool attachment point.

5.3 **Travel expenses.** Reimbursement for travel and subsistence expenses actually and necessarily incurred by the CONTRACTOR as a result of this Contract will be reimbursed out of the available administrative expense funds, with the exception of non-physician clinical CONTRACTOR staff that travel to attend required DOC meetings or to fulfill clinical duties, which will be paid from the staffing fund. Pursuant to the above, the CONTRACTOR will be reimbursed for mileage and meal expenses in the same manner and in no greater amount than provided in the current "Commissioner's Plan," as amended from time to time, established by the Commissioner of Minnesota Management and Budget, which is incorporated in to this Contract by reference. The CONTRACTOR will not be reimbursed for travel and subsistence expenses incurred outside Minnesota unless it has received the State's prior written approval for out-of-state travel. Minnesota will be considered the home state for determining whether travel is out of state.

5.4 **Total obligation.** The total obligation of the State for all compensation and reimbursements to the CONTRACTOR under this Contract will not exceed $67,146,118. State variable costs not reflected in this base amount include costs for inmate populations exceeding 9000, staffing fund adjustments and risk share obligations.

5.5 **Payment.**

5.5.1 **Invoices.** The State will promptly pay the CONTRACTOR, in no case later than 30 days, after the CONTRACTOR presents an itemized invoice for the services actually performed and the State's Authorized Representative accepts the invoiced services, the approval of which shall not be unreasonably withheld. Invoices must be submitted twice-monthly based on Claims Expenses, Staffing Fund, unpaid Interstate claims, and Administrative Fees. The CONTRACTOR must provide all billing detail to DOC that provides the amount of unpaid Subcontractor invoices and the amount due to each Subcontractor as an appendix to the twice-monthly payment invoices.

5.5.2 **Retainage.** Statutory retainage has been waived by the State pursuant to Minn. Stat. § 16C.08. Ten percent (10%) contractual retainage will be withheld on administrative expenses. Retainage may be released on a per term basis if the administrative duties for that term have been performed and accepted pursuant to the Conditions of Payment clause, upon which time retainage will be released within 30 days of reconciliation of that term's administrative expenses.

5.6 **Administrative Expenses.** For the purposes of this Contract, the following services will be paid from the CONTRACTOR's administrative expenses: regional office and other contract costs, and the CONTRACTOR's corporate management, risk premium and Contract return costs.

5.7 **Staffing Fund.** The CONTRACTOR shall be responsible for establishing compensation levels for site providers and these providers shall be paid from the site staffing fund for clinical services performed and for approved activities while on a paid work status. Services will be provided in accordance with Attachment 3. The CONTRACTOR will be responsible for any shortfall in the staffing fund unless the shortfall is a result of requests by the State for provider hours in addition to those outlined in Attachment 3.

5.8 **Incentive Payments.** No monies shall be paid from the Staffing Fund for the purpose of recruiting or retention of CONTRACTOR's staff positions without the prior approval of the State. Examples of these types of expenditures would be moving expenses, contract buy-outs and sign-on bonuses. These expenditures shall be referred to as incentive payments. The DOC may approve, deny or propose an alternative to the CONTRACTOR's recommendation within two business days. DOC decisions regarding incentive payments have no bearing on the CONTRACTOR's responsibility for filling vacancies in accordance with the Contract language. In the event an employee who receives incentive compensation from the staffing fund is reassigned to a medical director position within one year of the commencement date for his/her original employment agreement, the CONTRACTOR shall reimburse the DOC in the amount of the incentive compensation initially paid to the employee.

6. **Conditions of payment**

All services provided by the CONTRACTOR under this Contract must be performed to the State's satisfaction, as reasonably determined at the sole discretion of the State's Authorized Representative and in accordance with all applicable federal, state, and local laws, ordinances, rules, and regulations including business registration requirements of the Office of the Secretary of State. The CONTRACTOR will not receive payment for work found by the State to be reasonably unsatisfactory or performed in violation of federal, state, or local law.

7. **Authorized Representative**

7.1 The State's Authorized Representative is Nanette M. Larson, Director of Health Services, Minnesota Department of Corrections, 1450 Energy Park Drive, Suite 200, St. Paul, MN 55108, or her successor and/or assignee, and has the responsibility to monitor the CONTRACTOR's performance and the authority to accept the services provided under this Contract. If the services are satisfactory, the State's Authorized Representative will certify acceptance on each invoice submitted for payment.

7.2 The CONTRACTOR's Authorized Representative is Steven H. Wheeler, CEO at the following business address and telephone number: 7700 Forsyth Blvd., St. Louis, MO 63105, or his successor and/or assignee. If the CONTRACTOR's Authorized Representative changes at any time during this Contract, the CONTRACTOR must immediately notify the State.

8. **Assignment, amendments, waiver, and contract complete**

8.1 **Assignment.** The CONTRACTOR may neither assign nor transfer any rights or obligations under this Contract without the prior consent of the State and a fully executed assignment agreement, executed and approved by the same parties who executed and approved this Contract, or their successors.

8.2 **Amendments.** Any amendment to this Contract must be in writing and will not be effective until it has been executed and approved by the same parties who executed and approved the original Contract, or their successors.

8.3 **Waiver.** If the State fails to enforce any provision of this Contract, that failure does not waive the provision or its right to enforce it.

8.4 **Contract complete.** This Contract, and its Exhibits, contains all negotiations and agreements between the State and the CONTRACTOR. No other prior understanding regarding this Contract, whether written or oral, may be used to bind either party. No additional provisions may be added to this contract except by formal amendment, in writing and executed by both parties.

9. **Indemnification**

9.1 In the performance of this Contract by CONTRACTOR, or CONTRACTOR's agents or employees, the CONTRACTOR must indemnify, save, and hold harmless the State, its agents, and employees, from any claims or causes of action, including attorney's fees incurred by the State, to the extent caused by CONTRACTOR's:

a) Intentional, willful, or negligent acts or omissions; or
b) Actions that give rise to strict liability; or
c) Breach of contract or warranty.

9.2 The indemnification obligations of this section do not apply in the event the claim or cause of action is the result of the State's sole negligence. This clause will not be construed to bar any legal remedies the CONTRACTOR may have for the State's failure to fulfill its obligation under this Contract. The DOC agrees to notify CONTRACTOR's Authorized Representative in writing no more than thirty (30) days after the DOC has received written notice of a claim, or any event, within such timeframe that does not prejudice CONTACTOR's ability to defend the claim.

10. **State audits**

Under Minn. Stat. § 16C.05, subd. 5, the CONTRACTOR's books, records, documents, and accounting procedures and practices relevant to this Contract are subject to examination by the State and/or the State Auditor or Legislative Auditor, as appropriate, for a minimum of six years from the end of this Contract.

11. **Government data practices and intellectual property**

11.1 **Government data practices.** The CONTRACTOR and State must comply with the Minnesota Government Data Practices Act, Minn. Stat. ch. 13, (or, if the State contracting party is part of the Judicial Branch, with the Rules of Public Access to Records of the Judicial Branch promulgated by the Minnesota Supreme Court as the same may be amended from time to time) as it applies to all data provided by the State under this Contract, and as it applies to all data created, collected, received, stored, used, maintained, or disseminated by the CONTRACTOR under this Contract. The civil remedies of Minn. Stat. § 13.08 apply to the release of the data governed by the Minnesota Government Practices Act, Minn. Stat. ch. 13, by either the CONTRACTOR or the State.

If the CONTRACTOR receives a request to release the data referred to in this clause, the CONTRACTOR must immediately notify and consult with the State's Authorized Representative as to how the CONTRACTOR should respond to the request. The CONTRACTOR's response to the request shall comply with applicable law.

11.2 **Data incident response requirements.** Upon discovery of an incident relating to the improper disclosure of non-public, private, or otherwise protected data, CONTRACTOR shall comply with all provisions of Minn. Stat. Ch. 13, and when not in conflict shall also perform as follows:

11.2.1 If the CONTRACTOR is aware or becomes aware that a data incident may have occurred with respect to DOC data, as governed by Minn. Stat. § 13.055, the CONTRACTOR will promptly notify the DOC's representative no later than twenty-four (24) hours after the CONTRACTOR becomes aware of a possible incident. If the CONTRACTOR becomes aware of incident on a weekend or holiday, CONTRACTOR will promptly notify the DOC on the first full business day following the weekend or holiday.

11.2.2 The DOC will review with the CONTRACTOR the scope of any data incident, and provide the CONTRACTOR the direction related to the appropriate subject notification, if necessary under Minn. Stat. § 13.055. All costs associated with the data incident will be the responsibility of the CONTRACTOR.

11.2.3 The CONTRACTOR will provide regular status reports to the DOC's representative or designee on the progress made in addressing the data incident.

11.2.4 To prevent the improper disclosure of non-public, private, or otherwise protected data release, any copy machine, or machine capable of producing a copy, that is replaced during the term of the agreement or upon termination of the agreement between the CONTRACTOR and the

DOC, will be sanitized by a copier vendor or other approved third-party. The CONTRACTOR is responsible to ensure that sanitation occurs and is performed to State standards.

11.2.5 The DOC and CONTRACTOR will develop a mutually agreeable written plan by April 1, 2014, to ensure that all data related to this Contract is returned to the DOC and properly sanitized by the CONTRACTOR per Department of Defense sanitation specifications should the DOC's relationship with the CONTRACTOR end. All costs associated with the sanitation will be borne by the CONTRACTOR.

11.3 Intellectual property rights.

11.3.1 Intellectual property rights. CONTRACTOR shall retain exclusive ownership of all CONTRACTOR Pre-Existing Intellectual Property, as defined hereto. "CONTRACTOR Pre-Existing Intellectual Property" is defined as: (a) all pre-existing technology and know-how protected by any patents or described in any patent applications, copyrights, trade secrets, trademarks, business methods, customer information, designs, graphics, inventions, developments, improvements and other intellectual property rights conceived, reduced to practice, discovered, invented, and/or developed exclusively by CONTRACTOR as of or prior to the Effective Date of this Contract; (b) any other pre-existing technology and know-how that CONTRACTOR claims a confidential proprietary interest in and to as of or prior to the date of the Contract even if it is not protected by a patent or described in a patent application; and (c) all pre-existing technology and know-how licensed to CONTRACTOR by third-parties as of or prior to the date of the Contract. CONTRACTOR Pre-Existing Intellectual Property does not include technology or know-how that is generally known or included in the public domain as of the date of this Contract. Excluding CONTRACTOR Pre-Existing Intellectual Property, the State owns all rights, title, and interest in all of the intellectual property rights, including copyrights, patents, trade secrets, trademarks, and service marks in the works and documents created and paid for under this Contract. The "Works" means all inventions, improvements, discoveries (whether or not patentable), databases, computer programs, reports, notes, studies, photographs, negatives, designs, drawings, specifications, materials, tapes, and disks conceived, reduced to practice, created or originated by the CONTRACTOR, its employees, agents, and sub-contractors, either individually or jointly with others during the performance of this Contract. "Works" includes documents. The "documents" are the originals of any databases, computer programs, reports, notes, studies, photographs, negatives, designs, drawings, specifications, materials, tapes, disks, or other materials, whether in tangible or electronic forms, prepared by the CONTRACTOR, its employees, agents, or sub-contractors, during the performance of this Contract. The documents will be the exclusive property of the State and all such documents must be immediately returned to the State by the CONTRACTOR upon completion or cancellation of this Contract. To the extent possible, those Works eligible for copyright protection under the United States Copyright Act will be deemed to be "works made for hire." The CONTRACTOR assigns all right, title, and interest it may have in the Works and the documents to the State. The CONTRACTOR must, at the request of the State, execute all papers and perform all other acts necessary to transfer or record the State's ownership interest in the Works and documents. CONTRACTOR shall grant State a nontransferable, limited, perpetual, royalty-free license to use the Pre-Existing Intellectual Property, which may be incorporated into the Works created for State under this Contract solely for its internal business purposes. During the Term of this Contract, CONTRACTOR shall grant State a nontransferable, limited, perpetual, royalty-free license to use any newly developed intellectual property or improvements to the CONTRACTOR Pre-Existing Intellectual Property that CONTRACTOR developed during and as a part of CONTRACTOR's performance under this Contract solely for its internal business purposes.

11.3.2 Obligations

a) Notification. Whenever any invention, improvement, or discovery (whether or not patentable) is made or conceived for the first time or actually or constructively reduced to practice by the CONTRACTOR, including its employees and sub-contractors, during the performance of this Contract, the CONTRACTOR will immediately give the State's Authorized Representative written notice thereof, and must promptly furnish the State's Authorized Representative with complete information and/or disclosure thereon.

b) Representation. The CONTRACTOR must perform all acts, and take all steps necessary to ensure that all intellectual property rights in the Works and documents are the sole property of the State, and that neither CONTRACTOR nor its employees,

agents, or sub-contractors retain any interest in and to the Works and documents. The CONTRACTOR represents and warrants that the Works and documents do not and will not infringe upon any intellectual property rights of other persons or entities. Notwithstanding Clause 8, the CONTRACTOR will indemnify; defend, to the extent permitted by the Attorney General; and hold harmless the State, at the CONTRACTOR's expense, from any action or claim brought against the State to the extent that it is based on a claim that all or part of the Works or documents infringe upon the intellectual property rights of others. The CONTRACTOR will be responsible for payment of any and all such claims, demands, obligations, liabilities, costs, and damages, including but not limited to, attorney fees. If such a claim or action arises, or in the CONTRACTOR's or the State's opinion is likely to arise, the CONTRACTOR must, at the State's discretion, either procure for the State the right or license to use the intellectual property rights at issue or replace or modify the allegedly infringing Works or documents as necessary and appropriate to obviate the infringement claim. This remedy of the State will be in addition to and not exclusive of other remedies provided by law.

c) Expiration. Notwithstanding the foregoing, upon termination or expiration of this Contract, CONTRACTOR shall, upon request, provide DOC with any and all inmate health information or data contained in any proprietary, Contractor-owned, or third-party software programs.

11.4 Confidentiality

11.4.1 The State hereby acknowledges that certain information and documents provided by CONTRACTOR and/or used by CONTRACTOR in fulfilling its Contract obligations are deemed by CONTRACTOR to be proprietary, confidential, and constitute trade secrets including, among other things, Policy and Procedure Manuals; Clinical Pathways; Personal Policy manuals; Employee Information; and Financial Information.

11.4.2 The State hereby agrees to keep confidential all CONTRACTOR documents that constitute trade secret data as defined by or are otherwise protected under the Minnesota Data Practices Act, Minn. Stat. Ch. 13. The State further agrees to limit the access to such trade secret or otherwise protected data strictly to employees and representatives (such as attorneys or consultants) who have a need to know the Confidential or Proprietary Information and who have been informed of the obligation to keep such information or documents confidential.

11.4.3 The State further agrees that any confidential information or documentation will not be disclosed to third parties unless CONTRACTOR specifically authorizes disclosure in advance, so that CONTRACTOR may have the opportunity to intervene to protect its Confidential and Proprietary Information from public disclosure.

11.4.4 The terms contained in Section 11.4 of this Contract shall apply to the extent permitted by Minnesota law, and in particular, Minn. Stat. Ch. 13.

12. Insurance and litigation notice

12.1 Insurance. CONTRACTOR shall not commence work under the Contract until it has obtained all the insurance described below and the State of Minnesota has approved such insurance. CONTRACTOR shall maintain such insurance in force and effect throughout the term of the Contract. CONTRACTOR is required to maintain and furnish satisfactory evidence of the following insurance policies:

12.1.1 Workers' Compensation Insurance: Except as provided below, CONTRACTOR must provide Workers' Compensation insurance for all its employees and, in case any work is subcontracted, CONTRACTOR will require the Subcontractor to provide Workers' Compensation insurance in accordance with the statutory requirements of the State of Minnesota, including Coverage B, Employer's Liability. Insurance minimum limits are as follows:

$100,000 – Bodily Injury by Disease per employee
$500,000 – Bodily Injury by Disease aggregate
$100,000 – Bodily Injury by Accident

If Minnesota Statute 176.041 exempts CONTRACTOR from Workers' Compensation insurance or if the CONTRACTOR has no employees in the State of Minnesota,

CONTRACTOR must provide a written statement, signed by an authorized representative, indicating the qualifying exemption that excludes CONTRACTOR from the Minnesota Workers' Compensation requirements.

If during the course of the Contract the CONTRACTOR becomes eligible for Workers' Compensation, the CONTRACTOR must comply with the Workers' Compensation Insurance requirements herein and provide the State of Minnesota with a certificate of insurance.

12.1.2 **Commercial General Liability Insurance:** CONTRACTOR is required to maintain insurance protecting it from claims for damages for bodily injury, including sickness or disease, death, and for care and loss of services as well as from claims for property damage, including loss of use which may arise from operations under the Contract whether the operations are by the CONTRACTOR or by a Subcontractor or by anyone directly or indirectly employed by the CONTRACTOR under the Contract. Insurance minimum limits are as follows:

$2,000,000 – per occurrence
$2,000,000 – annual aggregate
$2,000,000 – annual aggregate – Products/Completed Operations

The following coverages shall be included:

Premises and Operations Bodily Injury and Property Damage
Personal and Advertising Injury
Blanket Contractual Liability
Products and Completed Operations Liability
Other, if applicable, please list: _____
State of Minnesota named as an Additional Insured, to the extent permitted by law

12.1.3 **Commercial Automobile Liability Insurance:** CONTRACTOR is required to maintain insurance protecting it from claims for damages for bodily injury as well as from claims for property damage resulting from the ownership, operation, maintenance or use of all owned, hired, and non-owned autos which may arise from operations under this Contract, and in case any work is subcontracted the CONTRACTOR will require the Subcontractor to maintain Commercial Automobile Liability Insurance. Insurance minimum limits are as follows:

$2,000,000 – per occurrence Combined Single limit for Bodily Injury and Property Damage

In addition, the following coverages should be included:

Owned, Hired, and Non-owned Automobile.

12.1.4 **Professional/Technical, Errors and Omissions, and/or Miscellaneous Liability Insurance** This policy will provide coverage for all claims the CONTRACTOR may become legally obligated to pay resulting from any actual or alleged negligent act, error, or omission related to CONTRACTOR's professional services required under the Contract.

CONTRACTOR is required to carry the following minimum limits:

$2,000,000 – per claim or event
$2,000,000 – annual aggregate

Any deductible will be the sole responsibility of the CONTRACTOR and may not exceed $100,000 per claim.

The retroactive or prior acts date of such coverage shall not be after the effective date of this Contract and CONTRACTOR shall maintain such insurance for a period of at least three (3) years, following completion of the work. If such insurance is discontinued, extended reporting period coverage must be obtained by CONTRACTOR to fulfill this requirement.

12.2 Additional Insurance Conditions:

12.2.1 CONTRACTOR's policy(ies) shall be primary insurance to any other valid and collectible insurance available to the State of Minnesota with respect to any claim arising out of CONTRACTOR's performance under this Contract;

12.2.2 If CONTRACTOR receives a cancellation notice from an insurance carrier affording coverage herein, CONTRACTOR agrees to notify the State of Minnesota within five (5) business days with a copy of the cancellation notice, unless CONTRACTOR's policy(ies) contain a provision that coverage afforded under the policy(ies) will not be cancelled without at least thirty (30) days advance written notice to the State of Minnesota;

12.3 CONTRACTOR is responsible for payment of Contract related insurance premiums and deductibles;

12.4 CONTRACTOR shall obtain insurance policy(ies) from insurance company(ies) having an "AM BEST" rating of A- (minus); Financial Size Category (FSC) VII or better, and authorized to do business in the State of Minnesota; and

12.5 An Umbrella or Excess Liability insurance policy may be used to supplement the CONTRACTOR's policy limits to satisfy the full policy limits required by the Contract.

12.6 The State reserves the right to immediately terminate the Contract if the CONTRACTOR is not in compliance with the insurance requirements and retains all rights to pursue any legal remedies against the CONTRACTOR. All insurance policies must be open to inspection by the State, and copies of policies must be submitted to the State's authorized representative upon written request.

12.7 CONTRACTOR is required to submit Certificates of Insurance acceptable to the State of MN as evidence of insurance coverage requirements prior to commencing work under the Contract.

12.8 **CONTRACTOR's current insurance policies**
At the time of the Contract Execution Date, CONTRACTOR has in place the following insurance policies that exceed the amounts required under Section 12.1:
Commercial General Liability and Professional Liability: $2M/claim; $6M/aggregate; and $10M/excess
Employment Practices Liability: $2M/claim; and $10M/excess

12.9 **Insurance of Subcontractors**
CONTRACTOR shall ensure that all Subcontractors carry, at a minimum, the following insurance amounts and name both CONTRACTOR and the DOC as additional insureds:
Commercial General Liability and Professional Liability: $1M/claim; and $2M/aggregate.
Automobile Insurance (if the Subcontractor will be utilizing automobiles to provide services to CONTRACTOR): $2M/claim; and $2M/aggregate.

12.10 **Litigation Notices**
CONTRACTOR agrees to notify DOC's Authorized Representative in writing no more than thirty (30) days after CONTRACTOR has received written notice of a claim or suit, or in any event, within such a timeframe that does not prejudice DOC's ability to defend same.

13. **Suspension and Debarment**

13.1 **Debarment by State, its departments, commissions, agencies, or political subdivisions**
CONTRACTOR certifies that neither it nor its principals is presently debarred or suspended by the State, or any of its departments, commissions, agencies, or political subdivisions. CONTRACTOR's certification is a material representation upon which the Contract award was based. CONTRACTOR shall provide immediate written notice to the State's Authorized Representative if at any time it learns that this certification was erroneous when submitted or becomes erroneous by reason of changed circumstances.

13.2 **Certification regarding debarment, suspension, ineligibility, and voluntary exclusion**
CONTRACTOR certifies that it is in compliance with federal requirements on debarment, suspension, ineligibility and voluntary exclusion specified in the solicitation document implementing Executive Order 12549. CONTRACTOR's certification is a material representation upon which the Contract award was based.

14. **Publicity and endorsement**

14.1 **Publicity.** Any publicity regarding the subject matter of this Contract must identify the State as the sponsoring agency and must not be released without prior written approval from the State's Authorized Representative. For purposes of this provision, publicity includes notices, informational pamphlets, press releases, research, reports, signs, and similar public notices prepared by or for the CONTRACTOR individually or jointly with others, or any sub-contractors, with respect to the program, publications, or services provided resulting from this Contract.

14.2 **Endorsement.** The CONTRACTOR must not claim that the State endorses its products or services.

15. **Change Control Process**
Notwithstanding anything herein to the contrary, if

15.1 any applicable law, statute, rule, regulation, standard, court order or decrees, or any policy, practice, or procedure of any applicable governmental unit, agency or office (including but not limited to the federal, state, or local courts, legislative bodies, and agencies, including the State or its respective officers or agents) is adopted, implemented, amended or changes; or if

15.2 any standard of care or treatment protocol changes or evolves in any material respect, or if any new medication or therapy is introduced to treat any illness, disease or condition. Then

15.3 any such change in scope as described in (a) or (b) materially affects the cost to the CONTRACTOR in providing health care services or impacts the scope of services or staffing hereunder, the CONTRACTOR and the State agree to negotiate in good faith to address any adjustment to compensation or service. The parties agree to meet and negotiate in good faith within thirty (30) days following written notice by one party to the other party of a change (whether such change is anticipated or implemented). Any modification that materially affects the cost to the CONTRACTOR or to the State must be agreed upon in writing and be made as a formal amendment to this Contract. Failure to reach an agreement within a reasonable period of time following notice by either party may result in (1) the withholding of services and payment for those services in dispute until such time as a resolution is reached; (2) the need to enter into mutually agreed upon non-binding arbitration; or (3) a triggering of the termination language contained herein.

16. **Governing law, jurisdiction, and venue**
Minnesota law, without regard to its choice-of-law provisions, governs this Contract. Venue for all legal proceedings out of this Contract, or its breach, must be in the appropriate state or federal court with competent jurisdiction in Ramsey County, Minnesota.

17. **Data disclosure**
Under Minn. Stat. § 270C.65, subd. 3 and other applicable law, the CONTRACTOR consents to disclosure of its social security number, federal employer tax identification number, and/or Minnesota tax identification number, already provided to the State, to federal and state agencies, and state personnel involved in the payment of state obligations. These identification numbers may be used in the enforcement of federal and state laws which could result in action requiring the CONTRACTOR to file state tax returns, pay delinquent state tax liabilities, if any, or pay other state liabilities.

18. **Payment to Subcontractors**

18.1 As required by Minn. Stat. § 16A.1245, the prime CONTRACTOR must pay all Subcontractors, less any retainage, within 10 calendar days of the prime CONTRACTOR's receipt of payment from the State for undisputed services provided by the Subcontractor(s) and must pay interest at the rate of one and one-half percent per month or any part of a month to the Subcontractor(s) on any undisputed amount not paid on time to the Subcontractor(s).

18.2 For the purpose of this Section, services shall be deemed undisputed upon:

18.2.1 Delivery of case-specific invoice to the CONTRACTOR, by the Subcontractor, for specific work performed;

18.2.2 Review by the CONTRACTOR of that invoice in accordance with the terms set forth in the Subcontractor agreement, and

18.2.3 Subsequent acceptance of said work in accordance with the terms set forth in the Subcontractor agreement at conclusion of the review period.

19. **Termination**

which the employment relates;
(2) that no CONTRACTOR, material supplier, or vendor, shall, in any manner, discriminate against, or intimidate, or prevent the employment of any person or persons identified in clause (1) of this section, or on being hired, prevent, or conspire to prevent, the person or persons from the performance of work under any contract on account of race, creed, or color;
(3) that a violation of this section is a misdemeanor; and
(4) that this contract may be canceled or terminated by the state, county, city, town, school board, or any other person authorized to grant the contracts for employment, and all money due, or to become due under the contract, may be forfeited for a second or any subsequent violation of the terms or conditions of this contract."

22. **Affirmative action requirements for contracts in excess of $100,000 and if the CONTRACTOR has more**

B. AMBULANCE SERVICES

The CONTRACTOR is responsible for all medical transfers by ambulance or medi-van, including airborne ambulance. The DOC shall provide all non-emergency medical transportation through a central or facility system. The DOC shall be responsible for coordinating this service. The CONTRACTOR shall coordinate and cooperate with the facility staff on routine medical transportation, as well as keep facility security staff aware of all emergency ambulance transfers. The DOC shall provide adequate security for ambulance transfers.

C. EKG SERVICES

The CONTRACTOR shall provide EKG services at all facilities. The CONTRACTOR shall be responsible for providing equipment and supplies, including permanent tracings for filing in the medical record, and performing the actual tracings and interpretations of the reports. Equipment provided shall be lightweight and portable. Stat EKG services must be available for Minnesota Correctional Facility (MCF)-Oak Park Heights. All EKGs shall be reviewed by a Board Certified cardiologist or alternative acceptable to the DOC. The CONTRACTOR shall ensure that all EKG machines are calibrated on an annual basis and documentation to ensure such calibration shall be provided to the DOC at their request.

D. IMAGING SERVICES

The CONTRACTOR shall provide imaging services such as x-ray and ultra sound at all DOC facilities. The CONTRACTOR shall also provide either on-site or off-site mammography services at MCF-Shakopee. The CONTRACTOR shall be responsible for providing supplies, scheduling and creating the images by a registered technician, interpretation by a Board Certified radiologist, and a written report. The CONTRACTOR shall also be responsible for all diagnostic imaging taken outside of the facilities.

E. LABORATORY SERVICES

The CONTRACTOR shall be responsible for all medical laboratory services, including supplies, forms and tests at all DOC facilities. The CONTRACTOR shall be responsible for transporting all specimens. STAT testing availability is expected at the Transitional Care Unit at MCF-Oak Park Heights. All STAT test results are expected to be timely and comparable to the Twin Cities' medical community standards. The DOC is responsible for payment for laboratory testing for forensic and other security purposes. The CONTRACTOR is responsible for reporting diseases to the Minnesota Department of Health as directed by regulation and statute.

F. PHLEBOTOMY SERVICES

The CONTRACTOR shall be responsible for all scheduled phlebotomy services for medically indicated draws at all facilities.

G. DIALYSIS

The CONTRACTOR shall be responsible for all dialysis services, whether provided on-site at facilities or off-site. The CONTRACTOR shall provide nephrology consultations, specialized nursing, pharmacy supplies, and equipment.

H. HIV/AIDS SERVICES

The CONTRACTOR shall provide all treatment of HIV/AIDS in a manner consistent with applicable standards of medical care, including CDC guidelines and Twin Cities' area community standard of care. The CONTRACTOR shall be responsible for all medical costs associated with the screening and treatment of HIV/AIDS.

I. TRANSITIONAL CARE UNIT (TCU) AND LINDEN UNIT

The CONTRACTOR and DOC Health Services Administrator (HSA) will be jointly responsible for the admission and discharge of all offenders to the TCU at MCF-Oak Park Heights. TCU discharges shall be made only Monday through Friday between the hours of 9:00 a.m. to 2:00 p.m. The CONTRACTOR shall also make all reasonable efforts to ensure that any discharges from the hospital to the facilities or TCU are made during the above stated times.
In the TCU, the CONTRACTOR shall conduct the following services:

1. Within 72 hours, all patients shall have a documented physical examination.
2. Diagnostic studies as clinically indicated.
3. Daily rounds (up to 7 days per week) by a practitioner for any patients admitted to the TCU, with appropriate documentation in the medical record. Physician's orders, progress notes, updated problem list and discharge summaries shall be completed during rounds.
4. Daily on-call physician coverage providing 24-hour services via telephonic response within fifteen (15) minutes of the call.

In the Linden Unit at MCF-Faribault, the CONTRACTOR will provide PCP services sufficient to conduct monthly rounds throughout the Linden Unit in addition to scheduled clinic appointments.

J. SPECIALTY SERVICES

The CONTRACTOR shall provide specialty services when medically indicated and supported by practice guidelines. The CONTRACTOR must provide all specialty services which could be needed, based on both correctional and community standards of care.

The CONTRACTOR shall design and implement a process for specialty referrals acceptable to the DOC. The process must include the use of commonly used practice protocols and guidelines. The CONTRACTOR must provide twelve copies of the protocols to the DOC prior to contract execution.
The CONTRACTOR must provide personnel to schedule specialty services. The scheduling process must include notification to the facilities as well as to the DOC's transportation staff. The CONTRACTOR shall track and analyze the time periods required for referral requests, written and/or verbal, and report to the DOC any requests that are deferred by the CONTRACTOR.

The CONTRACTOR shall submit samples of clinical guidelines and/or standards to be used in making decisions about the care to be provided to offenders. Guidelines submitted must be appropriate, responsible and reflect an understanding of the realities of providing health care to the offender population in Minnesota.

K. FIT TESTING

The CONTRACTOR shall ensure that appropriate CONTRACTOR personnel are "Fit Tested" so that medical care can be provided to offenders with communicable illnesses.

L. EMERGENCY MEDICAL CARE TO PERSONNEL, DEPARTMENT EMPLOYEES AND VISITORS

The CONTRACTOR shall provide but not be financially responsible for emergency medical care for all personnel and DOC employees in the event of accidents or incidents requiring emergency medical response. In addition, the CONTRACTOR is responsible for the emergency medical care provided to all visitors and any other persons on- site at the facilities. After the emergency, the CONTRACTOR may refer such personnel, DOC employees, and visitors and other persons to outside medical doctors or facilities, or to be followed by such persons' own physicians. The CONTRACTOR shall not be responsible for and shall not provide any routine health care for personnel, DOC staff, visitors or other persons on-site at the facilities.

M. THERAPEUTIC MEDICAL DIETS

The DOC offers a lacto-ovo alternative meal that meets the requirements of most medical diets. Practitioners shall consider the suitability of this option prior to ordering a special medical diet. Special medical diets shall he ordered and reviewed by a provider in consultation with the DOC dietitian as indicated. The DOC dietician will work with the food service managers to ensure special diets are provided. Nutritional supplements ordered by a practitioner will be paid for by the CONTRACTOR.

N. VISION CARE SERVICES

Routine Vision Care Services

Minnesota licensed optometrists shall be retained by the CONTRACTOR and shall offer routine vision care services within the facilities, to the extent possible based upon the availability of necessary equipment provided and maintained by the DOC.

Subsequent to an initial evaluation of routine vision care needs by an optometrist, based on nursing referral from the intake visual acuity screening, offenders will be afforded the opportunity to receive such services at intervals of no greater frequency than 2 years in accordance with guidelines of the American Optometric Association. Offenders 50 years of age or older and diabetic offenders will be afforded the opportunity to be examined by the optometrist at intervals of no greater frequency than annually.

In the event of identification of a special need which arose prior to the defined frequency intervals, such as a traumatic injury or a disease or disorder, which impacts vision, the offender may be evaluated by the optometrist more often than specified herein and referred to a physician based upon demonstrated clinical need.

Eyeglasses

Eyeglasses recommended by an optometrist for an offender shall he provided by the CONTRACTOR. Offenders in need of eyeglasses shall be provided with one pair of single vision or bifocal safety lenses (with lines) in a safety frame and lenses authorized by the DOC. Only offenders with an acuity value in either or both eyes above 20/40 shall be eligible for

corrective eyeglasses. Exceptions may be granted only with the approval of the CONTRACTOR's medical department based on a recommendation from the treating optometrist.

Contact Lenses and Tinted Lenses
Contact lenses and tinted lenses will be provided by the CONTRACTOR only in response to a legitimate medical need (e.g., when the vision is not sufficiently correctable with eyeglasses to maintain routine function) as clinically determined and recommended by an ophthalmologist with the approval of the CONTRACTOR's utilization review department and the DOC.

Replacement
Replacement of eyeglasses or contact lenses provided by the CONTRACTOR shall not occur more frequently than the time intervals for re-evaluation by an optometrist. If the eyeglasses or contact lenses are lost or damaged due to negligence by the offender, the offender will be responsible for the cost of replacement. If the inmate is determined indigent by the DOC, the cost of replacement shall be made from the risk share. The CONTRACTOR may provide a replacement only when the need occurs through no fault of the offender and only with clinical necessity and authorization of the CONTRACTOR's medical department. Any exceptions to this must be approved by DOC.

O. PHARMACY

The CONTRACTOR shall provide all prescription pharmaceuticals for the offenders prescribed by the CONTRACTOR's personnel or eligible DOC health care staff. The CONTRACTOR must also arrange for back-up pharmacy services if prescriptions must he started prior to when they can be obtained by the contract pharmacy. Cost for obtaining and delivery of back up pharmacy items is the CONTRACTOR's responsibility.

The CONTRACTOR shall provide a consulting pharmacist to visit each facility on a monthly basis for review of drug interactions, cost containment, drug disposal and assurance of quality control and regulatory compliance.

Reviews of non-formulary medication requests shall be made within 24 hours of such request or on the next business day.

Areas of concern or interest are identified through the Pharmaceutical & Therapeutics (P&T) Committee, Board of Pharmacy requirements, and DOC policies. The CONTRACTOR shall provide a consulting pharmacist to participate on the P &T committee.

The CONTRACTOR shall, during the first 3 months of the contract, meet all Minnesota Board of Pharmacy standards or work with the Board of Pharmacy to obtain any necessary and appropriate variances.

The CONTRACTOR shall provide reports on pharmacy utilization and prescribing practices as requested by the DOC.

The CONTRACTOR shall provide over the counter medication prescribed by the CONTRACTOR's personnel or eligible DOC health care staff. Prescribers shall comply with Division Directive 500.2011 Title: Over-the-Counter Medications (OTC).

Release Medications
CONTRACTOR shall ensure the following practice: At the time of release from a correctional facility, each offender is given a seven-day supply (or remainder of current prescription, whichever is greater) of medications unless otherwise restricted. Offenders must also receive written prescriptions for an additional thirty-day supply of medications where it is responsible to do so or as requested by the DOC. A thirty-day supply of psychotropic medications will be required for release medications for offenders with severe and persistent mental illness and those otherwise on neuroleptic medications. All prescribers must obtain a Medicaid provider number.

P. HEPATITIS C TREATMENT

The CONTRACTOR shall provide services for the diagnosis and treatment of Hepatitis C within the then current treatment guidelines and then current Hepatitis C treatment protocols established by the DOC, as incorporated herein by reference. This includes requirements to perform liver biopsies, lab tests, medications, and psychiatry, and may change from time-time, at the discretion of the DOC.

Q. OFFENDER SPECIFIC EQUIPMENT

The STATE shall be responsible for the cost of all durable medical equipment not otherwise addressed in this contract that is intended for use on multiple offenders over time. Durable medical equipment shall be defined as medical equipment that was designed for repeated use, can withstand repeated use, and is not disposable in nature.

The STATE shall be responsible for the cost of non-durable medical supplies and equipment used in the provision of offender health care in the normal operations of the clinics. Non-durable medical equipment shall be defined as medical equipment or supply that was designed for single use, not reusable, and disposable in nature.

The CONTRACTOR, through the risk share, shall be responsible for practitioner ordered medical prosthetics and medical equipment intended for an individual's personal use. This includes medically ordered purchases, rental, or necessary repairs of artificial limbs, prosthetic eyes, custom wheelchairs, hearing aids, adaptive devices, specialized beds, and any other equipment specifically ordered for an individual. The possibility of use by another offender requiring similar or same custom-made medical equipment does not alter the status of the equipment as custom-made, so long as that equipment is intended for the immediate use by a specific offender or for a specific offender's health needs. Non-durable medical supplies such as accessories and attachments for durable medical equipment such as but not limited to roho cushions, and masks and tubing forc-pap, bi-pap machines and physical therapy braces and splints will be the responsibility of the CONTRACTOR. Equipment provided by emergency rooms, hospitals or other off-site providers which meets utilization review criteria shall be funded from the risk share. Necessary repairs to an offender's personal prosthetic devices or equipment, such as wheelchairs shall be funded from the risk share as an alternative to replacing such property with new devices or equipment.

The CONTRACTOR shall be responsible for the cost of all other practitioner ordered medical equipment and supplies not herein defined, with same to be funded from the risk share. Should the CONTRACTOR and the STATE disagree on whether the equipment is the CONTRACTOR's

or the STATE's responsibility, the CONTRACTOR's regional manager and the STATE's contract monitor will mutually determine who is responsible for the cost of such equipment.

R. CONTINUITY OF OPERATIONS PLANNING

The CONTRACTOR shall provide a comprehensive continuity of operations plan to the DOC prior to contract execution. This provision shall be consistent with MDOC Policy 105.012, *Continuity of Operations*; Division Directive 500.012.

S. DENTAL SERVICES

The CONTRACTOR shall provide dental services consistent with DOC policy on an as needed basis. From time to time, the DOC may have an emergent need for dental services due to unexpected vacancies in the STATE dentist positions. The CONTRACTOR may be asked to provide dental services at an additional cost to the STATE should this need arise and should the CONTRACTOR be able to recruit qualified dentists to provide these services.

T. PSYCHIATRIC SERVICES

The CONTRACTOR shall provide competent and appropriate psychiatric assessment and ongoing care at each facility for offenders. The CONTRACTOR may utilize a mixture of qualified primary care providers and psychiatric nurse practitioners and board certified or eligible psychiatrists in meeting the provider hour criteria per the ratios provided and attached to this contract. Initial psychiatric assessments and the ongoing care for especially complex psychiatric cases must be provided by board certified or eligible psychiatrists at all facilities. Routine and follow-up psychiatric care may be provided by non-psychiatrist providers.

The percentage of psychiatric hours provided by non-psychiatrist providers is not to exceed 50% at any site. Because of the more challenging clinical environments at the MCF-OPH and MCF-SHK, the percentage of psychiatric service hours provided by non-psychiatrist providers is not to exceed 30% at these facilities. The percentage of psychiatric hours provided by non-psychiatrist providers (PC-PSY) at SCL and RW is not to exceed 40%. The CONTRACTOR is responsible for demonstrating the competence of non- psychiatrist providers to perform psychiatric services to the satisfaction of the DOC. Documentation of specialized training and experience, interviews and performance monitoring are examples of how competence may be demonstrated. Exceptions to these percentages may be made with the approval of the DOC.

Some DOC facilities maintain chemical dependency and/or sex offender treatment in addition to mental health services (which are available at all sites). There is relatively high comorbidity between these disorders within the DOC. In order to competently address the more complex clinical needs presented by offenders with multiple disorders and to provide psychiatric support for the DOC's treatment integration plans, the CONTRACTOR shall ensure that at least one psychiatric provider has competence in the provision of psychiatric services with populations with mental health, chemical dependency and sex offending concerns. This provider is to be available to provide consultation at any of the DOC sites either in person or by telemedicine.

Telemedicine: The DOC may acquire the equipment and software needed to facilitate telemedicine among Central Office and each of the facilities during the duration of this contract. Related to psychiatric services, telemedicine will not be an acceptable option for routine psychiatric care. DOC telemedicine equipment, if available at some point during this contract, would be made available to the CONTRACTOR at no cost for the purpose of providing

psychiatric care at DOC facilities, including: emergency psychiatric care, providing psychiatric coverage for a facility during brief periods agreed to by the DOC when no other practical options are available (i.e., interim coverage following the departure of a provider), or consultation on complex cases by a psychiatric provider with specialized expertise.

Teamwork and consultation: Psychiatric providers are considered part of treatment teams within the DOC and are expected to consult with medical, nursing, behavioral health and other DOC staff as needed to provide comprehensive treatment and continuity of care. It is expected that psychotropic medication will be prescribed based on verification of reported symptoms, summary file review, formal assessments provided by qualified DOC behavioral health staff relevant to the stated purpose of the referral. Psychiatric providers are expected to participate as requested in behavioral health and health services staffing meetings for the purpose of mutual consultation and education.

Productivity: Barring other barriers to the provision of treatment (i.e., facility lock-down), psychiatric providers are generally expected to meet productivity standards:
New Assessment: 40-45 minutes
Follow-up Assessment: 15-20 minutes
Chart Review: 5 minutes

Documentation: Providers are expected to dictate or write clinical notes and orders on the same day services are provided. Providers are expected to use SOAP note format for all follow-up assessment notes. Initial assessments shall minimally contain the following content areas:
Presenting problem
Current medications (if any)
Medication history
Psychiatric history
Current symptoms
Physical health
5 Axis Diagnoses
Summary
Plan
Referrals

U. ELECTRONIC HEALTH RECORDS

The DOC intends to begin utilizing an EHR to comply with state and federal mandates. The CONTRACTOR will be encouraged to provide input into the design and implementation stages of this project but will have no contractual obligation in this regard. The DOC will provide the CONTRACTOR's personnel training on any new record keeping systems. The CONTRACTOR is expected to utilize the DOC EHR systems as it is implemented.

V. E-MAR

The DOC is currently using an electronic medication ordering and administration system utilizing bar code scanning technology. The CONTRACTOR shall provide a similar automated system.

W. AUDIOLOGY SERVICES

The CONTRACTOR shall provide the continuum of audiology services, including hearing tests, hearing aids, fitting, adjustments, repair and batteries.

X. SOFTWARE APPLICATIONS

The CONTRACTOR shall offer value added programs, as identified in its response, at no additional cost to the DOC. Programs that require no DOC resources to implement and use are authorized by this contract. Programs that require ongoing commitment of time or labor by DOC employees shall require written approval by the DOC prior to implementation. The DOC has full discretionary authority to refuse to allow implementation of any value added program. Examples of such programs are contained in the chart:

RFP Reference Examples	Identifier/Name	Description
Executive Summary, Section 2. A. On-Site Services	TruCare	Used to isolate and target offenders having unique risk characteristics, and to deliver specific care management programs for those offenders.
Executive Summary, Section 2. B. Ambulance Services	Centelligence	Analytics tool, which uses clinical, risk, and administrative profile information obtained from medical, pharmacy, and lab data to proactively identify offenders with high risk profiles that require clinical management in order to prevent or minimize future costs.
Executive Summary, Section 2. Q. Hepatitis C Treatment.	CentAccount	Monetary rewards to offenders for targeted healthy behaviors.
Executive Summary, Section 2. Q. Hepatitis C Treatment.	Nurtur	Provides flexible and customized programs for wellness, disease management, episodic/catastrophic care management consultation, life resource information, education and training materials, and consultation.
Executive Summary	Impact Pro	Allows identification of care opportunities by using a mix of rigorous proprietary algorithms, including risk stratification, identifying adverse trends and care gaps, and combining these algorithms with evidence based medicine guidelines.
Section 2. N. Therapeutic Medical Diets.	Nurtur Dietitians	Nutritional educational handouts and opportunities to help the offender population understand that dietary choices play a significant role in health outcomes. Provider and MDOC health care staff training resources and innovative ways to get the dietary message to the offender.
Section 2. W. E-Mar.	Sapphire Health eMAR	Electronic medication administration record

ATTACHMENT 2
ADMINISTRATIVE SERVICES

The CONTRACTOR is responsible for addressing the following administrative requirements to ensure adequate coverage for the delivery of health care services and customer service. The CONTRACTOR must establish a system that blends its personnel and staff with the DOC staff (primarily nursing and psychology and dental) and include a process for issue resolution to respond to operating or coordination problems.

STAFFING

A. STAFFING MATRIX

The CONTRACTOR shall provide a staffing matrix clearly articulating the staffing necessary to provide the required services. In order to provide adequate and sufficient personnel to fulfill its obligations under this RFP, the CONTRACTOR shall recruit and retain, whether as employees, independent CONTRACTORs or otherwise, physicians, physician's assistants, nurse practitioners, occupational and physical therapists, ancillary providers, consultative and administrative personnel and such other personnel as the CONTRACTOR deems appropriate.

The CONTRACTOR shall complete a staffing plan that identifies the number and type of staff by shift that they will provide to meet the expectations of the RFP. If the DOC determines the approved staffing plan is inadequate in practice to meet the offender health care needs, the CONTRACTOR must modify the provider coverage to ensure that timely services are provided.

B. STAFFING LEVEL CHANGES

Staffing level changes as may be necessitated from time to time are to be determined by the mutual agreement of the CONTRACTOR and the DOC with the appropriate adjustments to compensation, if necessary. Such changes shall be implemented with the written approval of the DOC, and reflected by appropriate amendments to the contract, if necessary. Mutually agreed upon staffing level adjustments that do not require funding increases may be approved in writing by the DOC and do not require a contract amendment.

C. LICENSURE AND CREDENTIALING

The CONTRACTOR shall ensure that all personnel are currently licensed, certified, and/or registered to the extent required by the State of Minnesota and as necessary for the CONTRACTOR to fulfill its obligations under this contract. The DOC shall not bear financial responsibility for the cost of any required education to obtain or maintain such credentialing.

Physician Credentialing
The CONTRACTOR shall conduct credentialing of all personnel who are physicians, to the extent required by Minnesota law and other pertinent regulatory authorities, and must submit satisfactory evidence prior to the date that the physician commences the provision of services at a facility. The CONTRACTOR shall have a written policy and procedure regarding the physician credentialing process approved by the DOC. Each physician credential file shall contain, at a minimum, the following documents:

1. Copy of verified Minnesota license to practice medicine;

2. Copy of application for initial or renewal registration;
3. Copy of Federal controlled substance registration;
4. Evidence of malpractice insurance with claims and/or lawsuits pending or closed during the past ten years verified by the insurance carrier;
5. Copies of verified medical education documentation including medical school, internship, residency and fellowship programs;
6. Ten-year employment history, present and past, where the physician has practiced and reasons for change;
7. Evidence of reasonable inquiry into employment history with emphasis on assessment of clinical skills;
8. Evidence of recent TB testing and results;
9. Signed release of information form;
10. Information regarding any criminal proceedings;
11. A report from the National Practitioner Data Bank; and
12. Medicaid Provider number and NPI number.

A physician shall not commence services with the DOC while the full credentialing process continues or without evidence of a current Minnesota license to practice, evidence of current DEA registration, evidence of current TB testing, and evidence of current malpractice insurance at a minimum. Specialty clinic physicians, retained by the CONTRACTOR on a part time basis, who have privileges at a licensed Minnesota hospital may substitute documentation from said hospital if such documentation indicates conformance with Minnesota law.

Each physician shall be re-credentialed every two (2) years. All credential records, both for active and inactive physicians, shall be the property of the DOC, but shall be maintained by the CONTRACTOR at its corporate office and by the DOC Health Services Unit. A periodic audit of the credential files shall be conducted by a representative of the DOC. After the expiration or termination of the contract, the credentialing records will be given to the DOC and the CONTRACTOR shall have access to and may copy any such credentialing records.

The provisions of this section shall survive the termination or expiration of the contract.

Credentialing of Other Providers

Nursing Credentialing

All nursing personnel must have graduated from an accredited nursing program and hold applicable Minnesota licenses and advanced degrees. Nursing personnel shall not commence employment without evidence of a current Minnesota license to practice, evidence of current DEA licensure, where applicable, practice agreements with a Minnesota licensed physician, Medicaid number and NPI number, evidence of malpractice insurance coverage and evidence of current TB testing.

Ancillary Staff Credentialing

All other ancillary personnel, including but not limited to x-ray technicians, physical therapists, occupational therapists, phlebotomists, optometrists, podiatrists, infectious disease expert, and/or nursing assistants, must meet applicable Minnesota regulatory requirements and community certification training standards. Evidence of malpractice insurance coverage and current TB testing shall be provided.

D. SECURITY CLEARANCE

All contract personnel must receive security and background clearance by the DOC prior to provisions of services. This includes a criminal background check. The DOC will not unreasonably withhold or delay such clearance.

E. ORIENTATION

Personnel assigned to the facilities must participate in DOC sponsored orientation classes prior to providing services at a facility, and attend DOC training classes that, from time to time, may be reasonably required. Part time personnel will attend orientation and training as determined by the DOC. The CONTRACTOR's regional office staff (regional medical director, manager and clerical) must attend the DOC orientation academy.

F. APPLICATION OF DEPARTMENT RULES

Contract personnel shall comply with all DOC policies and shall be subject to the rules and standards of conduct set forth in the DOC's policies.

G. HIRING AND FIRING AND SUBCONTRACTOR TERMINATION

The CONTRACTOR shall have the right to hire and fire or terminate the employees or subCONTRACTORs, except that the CONTRACTOR shall not employ for the purposes of carrying out its obligations under this contract any person who is simultaneously employed by the State of Minnesota or any agency thereof.

The DOC may deny entrance of any of the CONTRACTOR's personnel to any or all facilities. The DOC shall notify the CONTRACTOR's program/regional manager of such denial and the reasons therefore as soon as reasonably practicable.

If the DOC is dissatisfied with any personnel provided by the CONTRACTOR to provide services under the contract, the CONTRACTOR shall resolve the problem to the DOC's satisfaction, including replacement of the personnel within a reasonable amount of time. If necessary, the CONTRACTOR must supplement the position with appropriate temporary personnel until the CONTRACTOR can secure a permanent replacement.

H. REGIONAL MANAGER

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a regional manager.

I. STATEWIDE MEDICAL AND PSYCHIATRIC DIRECTOR

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a physician to act as Statewide Medical Director. The Medical Director must be licensed in Minnesota and Board Certified in one of the following: Internal Medicine, Family Practice, Surgery, Preventive Medicine, or Emergency Medicine.

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a physician to act as Statewide Psychiatric

Director. The Psychiatric Director must be licensed in Minnesota and Board Certified in psychiatry.

J. TRANSLATION SERVICES

The CONTRACTOR shall provide translation services, when required, to meet the needs of the offender population. Offenders cannot be utilized as translators.

K. COMPENSATION AND BENEFITS OF PERSONNEL

The CONTRACTOR shall have the responsibility for determining the compensation, terms and conditions of employment or engagement and benefits of, and for paying all compensation and other benefits to the personnel. Hourly rates of compensation for each category of personnel, including independent CONTRACTORs, shall be submitted to the DOC on an annual basis. DOC staff may act as advisors to the CONTRACTOR in determining compensation and benefits. Annual increases, bonuses, moving expenses and/or any incentives provided to the CONTRACTOR's personnel must be approved by the DOC.

L. DEPARTMENT ACCESS TO PERSONNEL, PAYROLL, RECORDS AND UTILIZATION CLAIMS DATA

Upon reasonable prior notice, the DOC may review at the CONTRACTOR's offices the employment applications, resumes and personnel files of the personnel during regular business hours. At the request of the DOC, the CONTRACTOR shall provide a list of the names and home addresses and telephone numbers of all personnel.

The CONTRACTOR shall provide copies of subcontracts and payroll hours by facility each month.

M. MEDIA RELEASES

While the CONTRACTOR may be required by government regulation to make certain public disclosures, the CONTRACTOR or CONTRACTOR's personnel shall not issue press or media releases regarding the program, the DOC or the contract, except in coordination with designated staff in the DOC Commissioner's office, and pursuant to the terms of the Contract, DOC policies, and applicable law.

N. STAFF MEETINGS

The CONTRACTOR shall ensure that personnel attend all staff meetings as required by the mutual agreement of the CONTRACTOR's Regional Manager and the DOC, including, but not limited to: facility biweekly meetings, quality assurance, mortality reviews, risk management, peer review, Pharmaceutical & Therapeutics Committee and meetings pursuant to medical and professional staff organization bylaws and rules.

O. SERVICES FOR OTHERS

This RFP shall not prevent any personnel from providing or performing services for others, nor shall this contract in any way restrict the CONTRACTOR from using personnel to provide the services or any other services for others. No personnel providing direct care

services to offenders at facilities shall work more than one full- time equivalent, i.e., 40 hours per week, with the exception of the physician who is on-call for the system. Compensation for this responsibility is determined by the CONTRACTOR. The clinic hours at each site vary. However, the personnel must provide hours of services during the regularly scheduled clinic hours.

P. REGIONAL OFFICE

The CONTRACTOR shall establish and maintain a corporate office in the greater Twin Cities metropolitan area sufficient to meet contractual obligations if the CONTRACTOR is providing multiple services at multiple sites or if the DOC believes that it is in its best interest to have regional staff. Regional office staffing shall include, at least, the following positions and program functions:

1. One regional manager;	1.0
2. One statewide medical director;	1.0
3. One psychiatric director,	.6
4. Two schedulers,	2.0
5. One utilization management nurse;	1.0
6. One CQI/special projects nurse,	1.0
7. One office manager	1.0
	7.6

The credentials of all regional office management staff shall be submitted by the CONTRACTOR to the DOC, and approved in writing by the DOC, prior to January 1, 2014 and thereafter whenever a vacancy in said staff shall occur.

Q. ON-CALL COVERAGE

The CONTRACTOR shall designate a physician for on-call to include house call services for the system 24 hours per day, 7 days per week. The CONTRACTOR shall provide the DOC monthly on-call schedules in advance of the month if more than one physician will be on-call. The on-call physician is expected to respond within 15 minutes. Treatment for injuries requiring suturing and/or minor surgical procedures shall be provided on-site when possible. House call and call back services may be implemented to eliminate off-hour ER visits more appropriately handled at the facilities.

The CONTRACTOR shall provide an additional level of on-call psychiatric coverage 24 hours a day, 7 days a week. Our psychiatric on-call coverage will be available to each facility and enable facility-based staff to obtain direct and rapid after-hours resolution to behavioral and psychiatric crises. Psychiatric on-call coverage schedules will be posted and distributed as part of physician on-call coverage schedules to ensure that nursing and other DOC staff has a single on-call provider schedule.

All services provided under this section must be performed by local Minnesota licensed providers with knowledge and experience in Minnesota's correctional environment.

ATTACHMENT 3
SITE STAFFING MATRIX

Facility	PCP	PT	OB/GYN	ID	Phl	DTN	VFT	OPT	PPCP	NPP	CNS	PSY	PA/NP	Total Hrs/Wk
OPH	40		-		6			4	-			32	16	98
STW	80	-	-	-	8			4	-	8		16		116
SCL	32	-	-	-	-			8	-	12		30	-	82
LL	40	-	-	-	6			4			8	24	16	98
FRB	72	-	-	-	-			8	-	8		24	32	144
ML/WR	24	-	-	-	6			3	2			8	20	63
SHK	32	-	8	-	8			2	-	4		16	20	90
RW	2	-	-	-	-			2		3		6	8	21
RC	20	-	-	-	4			4		8		10	16	62
PRN @ All Sites														
Cost Center														
Regional Office	-	80	-	10	-	20	2	-	-			-		112
Grand Total	342	80	8	10	38	20	2	39	2	43	8	166	128	886

KEY	
PCP	Primary Care Provider
PT	Physical Therapist (All Facilities - assigned to the Regional Office)
DTN	Dietician
VFT	Visual Field Technician (All Facilities - assigned to the Regional Office)
Opt	Optometrist
NPP	Nurse Practitioner Psych
PPCP	Psychiatrist PCP (a PCP who performs psychiatry services)
Psy	Psychiatrist
CNS	Clinical Nurse Specialist - Psych
PA/NP	Physician Assistant/Nurse Practitioner
Phl	Phlebotomist
ID	Infect. Disease Specialist - All facilities, assigned to the Reg. office)

ATTACHMENT 4
FACILITIES COVERED AS PART OF THIS AGREEMENT

CONTRACTOR shall provide services, as identified herein, to the following facilities::

- MCF-Oak Park Heights
- MCF-Stillwater
- MCF-St. Cloud
- MCF-Lino Lakes (excluding work release and ICWC inmates)
- MCF-Faribault
- MCF-Moose Lake/Willow River
- MCF-Shakopee
- MCF-Red Wing
- MCF-Rush City
- Dakota County (juvenile girls committed to the MN Commissioner of Corrections only)

ATTACHMENT 5

Minnesota State Correctional Facilities
Daily Adult Facility Offender Population Report for 00/00/0000

	MALES										FEMALES			Grand
	OPH	SCL	STW	RC	FRB	LL	WR	ML	RW	Total	TOGO	SHK	Total	Total
MN Commit	0	0	0	0	0	0	0	0	0	0	0	0	0	0
PSI Hold	0	0	0	0	0	0	0	0	0	0	0	0	0	0
CIP	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Non - MN Commit-Received	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interstate	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BOP Exchange	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Income Contract Received	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BOP	0	0	0	0	0	0	0	0	0	0	0	0	0	0
County	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COMS ON GROUNDS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
FACILITY ON GROUNDS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
RECONCILIATION DIFFERENCES	0	0	0	0	0	0	0	0	0	0	0	0	0	0
MN - Commit Sent														
Jail Short-Term	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Jail Long-Term	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hospital Short-Term	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Hospital Long-Term	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Escape	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Dual Commit	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Interstate	0	0	0	0	0	0	0	0	0	0	0	0	0	0
BOP Exchange	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Contract Beds - Sent	0	0	0	0	0	0	0	0	0	0	0	0	0	0
ICWC	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COMS OFF GROUNDS	0	0	0	0	0	0	0	0	0	0	0	0	0	0
COMS TOTAL AUTHORITY	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Facility Bed Capacity	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Facility Beds Occupied	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Over (Under) Capacity	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Fac Bed Change From	0	0	0	0	0	0	0	0	0	0	0	0	0	0
HOP* Change From	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Tot Bed Change From	0	0	0	0	0	0	0	0	0	0	0	0	0	0

*Housed Out of Facility (includes Jail Long-Term, FCF and County Jail Contracts under the authority of NCF-FRB and NCF-LL)

DOC30-

AMENDMENT NO. 1 TO SWIFT 70449

Contract Start Date:	10/16/13	Total Base* Contract Amount:	$67,146,118
Original Contract Expiration Date:	6/30/2016	Original Base* Contract:	$67,146,118
Current Contract Expiration Date:	N/A	Previous Amendment(s) Total:	N/A
Requested Contract Expiration Date:	N/A	This Amendment:	$0

*DOC variable costs not reflected above include costs for inmate populations exceeding 9000, staffing fund adjustments, and risk share obligations.

This amendment is by and between the State of Minnesota, through its Commissioner of Corrections ("STATE" or "DOC") and Centurion of Minnesota, LLC, whose designated mailing address is 7700 Forsyth Blvd., St. Louis, MO 63105 ("CONTRACTOR").

Recitals

1. The DOC has a contract with the Contractor identified as SWIFT ID 70449 ("Original Contract") to provide medical and psychiatric services to all incarcerated offenders, male and female, adult and juvenile, residing in facilities or committed to the care and custody of the DOC and to provide health care contract management services for the DOC.

2. The DOC and Contractor need to include language to address issues related to Medicaid, purchasing pharmaceuticals through MMCAP, clinic operation hours and liquidated damages.

3. The State and the Contractor are willing to amend the Original Contract as stated below.

Contract Amendment

In this Amendment, changes to pre-existing Contract language will use ~~strike-through~~ for deletions and underlining for insertions.

REVISION 1. Clause 2, "Definitions," sub-clause 2.1, "Inmates/Offenders" is amended as follows:

2.1 Inmates/Offenders

~~Includes only those persons enumerated in~~ The Daily Adult Facility Offender Population Report and as highlighted in Attachment 5, as attached and incorporated into this Contract, ~~plus juvenile males at Red Wing and furloughed Red Wing juveniles~~ is the official record of the offender daily count for purposes of billing. These numbers shall include Minnesota inmates housed in county facilities on legal writs and in other State and Federal correctional facilities under exchange programs. ~~The eligibility feed sent to the CONTRACTOR by the DOC does not determine the official daily inmate count.~~

All inmates as described in the foregoing, plus juvenile males at Red Wing and furloughed Red Wing juveniles, shall receive the services described in this Contract.

Minnesota inmates housed in other State and Federal correctional facilities under exchange programs shall be provided On-Site Care including prescription drugs by those State and Federal entities. Contractor shall be responsible for Off-Site Care for those Minnesota inmates, subject to Contractor's utilization management approval.

Inmates from other states residing in DOC correctional facilities under the Interstate Compact Contract shall receive all On-Site Care, including prescription drugs through this contract. CONTRACTOR is not responsible for Off-Site Care costs of inmates from other states residing in Minnesota under the Interstate Compact Contract.

REVISION 2. Clause 3, "Duties," sub-clause 3.1, "Contractor's Duties," paragraph 3.1.2, referencing Attachment 2, is amended as follows:

3.1.2 The CONTRACTOR shall be primarily responsible for making all decisions with respect to the type, timing, and level of services needed by inmates covered by the Contract, including, without limitation, the determination of whether an inmate is in need of clinic care, hospitalization, referral to an outside specialist, or otherwise in need of specialized care. However, the DOC retains oversight and ultimate responsibility for the health care services provided to inmates. If necessary, the DOC can and will override clinical decisions made by the CONTRACTOR's health care professionals to ensure the best possible outcome within the DOC's budgeting restraints and

to meet legal requirements. Except as herein otherwise provided, the CONTRACTOR shall be the primary supplier and/or coordinator (responsible for scheduling On-Site and Off-Site Care) of all medical and psychiatric consulting services, and as such shall have joint responsibility with the DOC for the implementation, modification, and continuation of any and all health care programs for inmates. Specific services are further set forth herein and in Attachment 1-A (On-Site Services), Attachment 2-A (Administrative Services), Attachment 3 (Site Staffing Matrix), and Attachment 4 (Facilities Covered as Part of this Agreement), all of which are attached and incorporated into this Contract.

REVISION 3. Clause 5, "Consideration and Payment," sub-clause 5.2, "Risk Pool Attachment Point," is amended as follows:

5.2. Risk Pool Attachment Point

5.2.1 As set forth in the RFP and CONTRACTOR's Response, the intent of the Risk Pool is for the parties to share in either the cost of Claims Expenses exceeding the Risk Pool attachment point for each Contract term or the savings if the cost of Claims Expenses is less than the Risk Pool attachment point for each Contract term.

5.2.2 ~~As the number of inmates covered by third-party health insurance, either public or private, is not known at this time, the parties intend to revisit the Risk Pool attachment point and credits for claims within six months of the Contract Performance Start Date. While~~ the STATE will be fully reimbursing providers for Medicaid eligible offenders, the DOC is responsible for funding the STATE Share of the reimbursement. The STATE Share portion of the reimbursement is based on the Federal Medical Assistance Percentage (FMAP), which determines how much of the reimbursement will be covered by the Federal government. The FMAP is a minimum of 50% and is the current FMAP for the State of Minnesota. Since the DOC is responsible for the non-Federally funded portion of the reimbursement, the STATE Share portion of the inpatient reimbursement for Medicaid eligible offenders will remain in the risk share. For claims incurred on or after January 1, 2014, the inpatient portion of the risk share will be reduced by the estimated Federally funded reimbursement so that only the STATE share amount DOC is responsible for remains in the risk share. A final reconciliation of the risk share based on the actual Federal matching percentage provided for Medicaid eligible offenders will be made no later than 6 months after the end of the contract period.

The DOC intends to fully reimburse the wholesalers who provide pharmaceuticals through Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP). The costs associated with the MMCAP pharmaceuticals or any other pharmaceutical costs paid directly by DOC will be deducted from the Risk Pool.

5.2.3 CONTRACTOR shall invoice DOC for the costs associated with the Risk Pool at least one time per Contract term and more often if requested by DOC. DOC shall retain and manage Risk Pool funds subject to the terms herein.

5.2.4 Claims Expenses will be reconciled at the end of each Contract term using the modified Risk Pool attachment point.

REVISION 4. Clause 5, "Consideration and Payment," sub-clause 5.5, "Payment" is amended as follows:

5.5 Payment

5.5.1 Invoices. The State will promptly pay the CONTRACTOR, in no case later than 30 days, after the CONTRACTOR presents an itemized invoice for the services actually performed and the State's Authorized Representative accepts the invoiced services, the approval of which shall not be unreasonably withheld. Invoices must be submitted twice-monthly based on Claims Expenses, Staffing Fund, unpaid interstate claims, and Administrative Fees. The CONTRACTOR must provide all billing detail to DOC that provides the amount of unpaid Subcontractor invoices and the amount due to each Subcontractor as an appendix to the twice-monthly payment invoices.

The STATE, with Federal support, will fully reimburse providers for offenders eligible for the Medicaid program. Therefore, the DOC will adjust the payment of the bi-monthly invoices by the total inpatient reimbursement by Medicaid for Medicaid eligible offenders. The DOC will adjust the payment of the bi-monthly invoices by the total actual drug costs of the pharmaceuticals purchased through MMCAP or other agencies.

REVISION 5. Clause 5, "Consideration and Payment," sub-clause 5.6, "Administrative Expenses" is amended as follows:

5.6 Administrative Expenses. For the purposes of this Contract, the following services will be paid from the CONTRACTOR's administrative expenses: regional office and other contract costs, and the CONTRACTOR's corporate management, risk premium and Contract return costs. Salary savings due to vacancies in the regional office staff positions will be refunded to the STATE if the position is vacant for longer than 60 days, with that 60 day period beginning on August 1, 2014.

REVISION 6. Clause 29, "Scheduling of Specialty, Diagnostic and Interventional Care appointments," sub-clause 29.1, regarding scheduling timeframes, is amended as follows:

29.1 CONTRACTOR will prospectively approve and schedule all specialty, diagnostic and interventional care except in cases of emergency. The CONTRACTOR will provide a medical records person or off-site services coordinator to handle paperwork (doctor's orders) and schedule appointments. CONTRACTOR will notify the appropriate DOC staff regarding appointment times in order to coordinate transportation and security. With the exception of emergency or urgent appointments, or clinically indicated (within 1 – 2 weeks), such notification will be provided at least four business days prior to the scheduled appointment. CONTRACTOR's internal approval process ("Utilization Management Review") must be completed within 44 7 calendar days of receipt of the referral by the CONTRACTOR.

REVISION 7. Clause 35, "Site Provider Liquidated Damages," is amended as follows:

35. Site Provider Liquidated Damages Language

35.1 For the purposes of Sections 33 and 34, vacancy will be defined as the absence of a contract with a practitioner to provide services as required by the site staffing matrix (Attachment 3) for the duties, hours and locations indicated. A contract to satisfy any vacancy will be deemed to achieve such, upon the filling of the same duties, hours and locations requirement of the prior practitioner's contract.

35.2 Site provider hours will be provided as negotiated by the DOC and CONTRACTOR, by Facility and by category of service (psychiatry, PCP and ancillary), provider class (psychiatrist, physician, midlevel, phlebotomist, etc.) as articulated in Attachment 3. CONTRACTOR intends to provide 100% of the staffing. The DOC acknowledges, however, that circumstances may arise where the CONTRACTOR does not fulfill all hours. Through the Staffing Fund, the DOC receives back 100% of all unspent dollars for compensation and benefit hours. To deter excess absences, the following non-compliance items are established:

35.2.1 All Positions

a) First 30 days of vacancy - no sanction

b) Vacancy from Day 31 through Day 90 - ~~30%~~ 30% of hourly rate for all hours of each shift which is not covered.

c) Vacancy from Day 91 and thereafter – 40% of hourly rate for all hours of each which is not covered.

35.3 Any single vacancy may be filled by a locums tenens provider. However, if a vacancy has been filled by a locums tenens provider for more than 90 consecutive days, the CONTRACTOR will reimburse such provider's services ~~50%~~ 60% from the Staffing Fund and ~~50%~~ 40% from the Administrative Expenses.

35.4 Hours or shifts not worked or scheduled due to routine and reasonable use of vacation or sick days, holidays, security (lock-down), acts of God or other extraordinary situations shall not be subject to sanctions. Should a position become vacant due to lockout, sanctions will not be applied against that position for the first 30 days of vacancy. As non-psychiatry positions have sanctions liquidated damages applied based upon scheduled shifts, CONTRACTOR may submit an amended schedule prior to the first day of the month of service that details additional shifts to be covered between the 15th and 31st day of the month of service.

35.5 CONTRACTOR shall provide weekly information in writing to DOC relating to the diligent efforts taken to fill vacant positions. The DOC contract monitor may approve exceptions to these liquidated damages resulting from unusual circumstances in consultation with the CONTRACTOR regional manager and the DOC medical director.

Except as amended herein, the terms and conditions of the Original Contract and all previous amendments remain in full force and effect.

1. STATE ENCUMBRANCE VERIFICATION

Individual certifies that funds have been encumbered as required by Minn. Stat. §§16A.15 and 16C.05.

Signed: Cindi Thomas

Date: 1/13/2015

SWIFT Contract No. 70449

2. CONTRACTOR

The Contractor certifies that the appropriate person(s) have executed the contract on behalf of the Contractor as required by applicable articles, bylaws, resolutions, or ordinances.

By:

Title: CEO

Date: 1/22/2015

By: _____

Title: _____

Date: _____

3. STATE AGENCY

Individual certifies the applicable provisions of Minn. Stat. §16C.08, subdivisions 2 and 3 are reaffirmed.

By:

Title: Deputy Commissioner
(with delegated authority)

Date: 1/26/15

4. COMMISSIONER OF ADMINISTRATION

As delegated to Materials Management Division

By:

Date: 1/29/15

33490

Distribution:
Agency
Contractor
State's Authorized Representative - Photo Copy

Rev. 7/11

ATTACHMENT 1 - A
ON-SITE SERVICES

In the performance of this Contract, CONTRACTOR shall comply with all policies and directives of the Minnesota Department of Corrections (DOC), which are incorporated herein by reference, and may be found at http://www.doc.state.mn.us/DOCpolicy2/html/dpw_main.asp?opt=IE.

A. INTAKE SERVICES

The CONTRACTOR shall, when requested, provide intake health care services or health care screenings on all admitted offenders entering the DOC at all facilities. These services shall include, at a minimum, the following components:

- Emergency health care, as indicated,
- Diagnostic procedures as indicated, and
- Infectious disease screenings.

History and Physical Examinations
The CONTRACTOR shall provide the following types of physical examinations:

- Initial physical examinations within 14 days of an offender's intake to a department facility when significant health problems are identified upon admission. When no significant health problems are presented, the initial physical examination shall be completed within 30 days of arrival. Offenders who have been released from a department facility and returned after 3 months will be referred for a complete physical examination if clinically indicated.
- Periodic history and physical examinations in conformance with DOC policies;
- Challenge Incarceration Program eligibility history and physical examinations; and
- Other history and physical examinations as required and requested.

All history and physical examinations shall be performed and documented in accordance with DOC's policies. All history and physical examinations must include a "problem list", health care plan and any other necessary documentation to ensure the appropriate delivery of health care services.

Documentation shall be in the SOAP format for all medical documentation.

Daily Sick Call/Primary Care Provider (PCP) Clinic Services
Sick call/PCP clinic services shall be available to offenders within all facilities, including those in general population, special housing units, and segregation. The scheduling and frequency of sick call/PCP clinic will be determined by the DOC. The PCP must be available to make rounds in segregation or other restricted housing units at all facilities.

B. AMBULANCE SERVICES

The CONTRACTOR is responsible for all medical transfers by ambulance or medi-van, including airborne ambulance. The DOC shall provide all non-emergency medical transportation through a central or facility system. The DOC shall be responsible for coordinating this service. The CONTRACTOR shall coordinate and

cooperate with the facility staff on routine medical transportation, as well as keep facility security staff aware of all emergency ambulance transfers. The DOC shall provide adequate security for ambulance transfers.

C. EKG SERVICES

The CONTRACTOR shall provide EKG services at all facilities. The CONTRACTOR shall be responsible for providing equipment and supplies, including permanent tracings for filing in the medical record, and performing the actual tracings and interpretations of the reports. Equipment provided shall be lightweight and portable. Stat EKG services must be available for Minnesota Correctional Facility (MCF)-Oak Park Heights. All EKGs shall be reviewed by a Board Certified cardiologist or alternative acceptable to the DOC. The CONTRACTOR shall ensure that all EKG machines are calibrated on an annual basis and documentation to ensure such calibration shall be provided to the DOC at their request.

D. IMAGING SERVICES

The CONTRACTOR shall provide imaging services such as x-ray and ultra sound at all DOC facilities. The CONTRACTOR shall also provide either on-site or off-site mammography services at MCF-Shakopee. The CONTRACTOR shall be responsible for providing supplies, scheduling and creating the images by a registered technician, interpretation by a Board Certified radiologist, and a written report. The CONTRACTOR shall also be responsible for all diagnostic imaging taken outside of the facilities.

E. LABORATORY SERVICES

The CONTRACTOR shall be responsible for all medical laboratory services, including supplies, forms and tests at all DOC facilities. The CONTRACTOR shall be responsible for transporting all specimens. STAT testing availability is expected at the Transitional Care Unit at MCF-Oak Park Heights. All STAT test results are expected to be timely and comparable to the Twin Cities' medical community standards. The DOC is responsible for payment for laboratory testing for forensic and other security purposes. The CONTRACTOR is responsible for reporting diseases to the Minnesota Department of Health as directed by regulation and statute.

F. PHLEBOTOMY SERVICES

The CONTRACTOR shall be responsible for all scheduled phlebotomy services for medically indicated draws at all facilities.

G. DIALYSIS

The CONTRACTOR shall be responsible for all dialysis services, whether provided on-site at facilities or off-site. The CONTRACTOR shall provide nephrology consultations, specialized nursing, pharmacy supplies, and equipment.

H. HIV/AIDS SERVICES

The CONTRACTOR shall provide all treatment of HIV/AIDS in a manner consistent with applicable standards of medical care, including CDC guidelines and Twin Cities' area community standard of care. The CONTRACTOR shall be responsible for all medical costs associated with the screening and treatment of HIV/AIDS.

I. TRANSITIONAL CARE UNIT (TCU) AND LINDEN UNIT

The CONTRACTOR and DOC Health Services Administrator (HSA) will be jointly responsible for the admission and discharge of all offenders to the TCU at MCF-Oak Park Heights. TCU discharges shall be made only Monday through Friday between the hours of 9:00 a.m. to 2:00 p.m. The CONTRACTOR shall also make all reasonable efforts to ensure that any discharges from the hospital to the facilities or TCU are made during the above stated times.
In the TCU, the CONTRACTOR shall conduct the following services:

1. Within 72 hours, all patients shall have a documented physical examination.
2. Diagnostic studies as clinically indicated.
3. Daily rounds (up to 7 days per week) by a practitioner for any patients admitted to the TCU, with appropriate documentation in the medical record. Physician's orders, progress notes, updated problem list and discharge summaries shall be completed during rounds.
4. Daily on-call physician coverage providing 24-hour services via telephonic response within fifteen (15) minutes of the call.

In the Linden Unit at MCF-Faribault, the CONTRACTOR will provide PCP services sufficient to conduct monthly rounds throughout the Linden Unit in addition to scheduled clinic appointments.

J. SPECIALTY SERVICES

The CONTRACTOR shall provide specialty services when medically indicated and supported by practice guidelines. The CONTRACTOR must provide all specialty services which could be needed, based on both correctional and community standards of care.

The CONTRACTOR shall design and implement a process for specialty referrals acceptable to the DOC. The process must include the use of commonly used practice protocols and guidelines. The CONTRACTOR must provide twelve copies of the protocols to the DOC prior to contract execution.
The CONTRACTOR must provide personnel to schedule specialty services. The scheduling process must include notification to the facilities as well as to the DOC's transportation staff. The CONTRACTOR shall track and analyze the time periods required for referral requests, written and/or verbal, and report to the DOC any requests that are deferred by the CONTRACTOR.

The CONTRACTOR shall submit samples of clinical guidelines and/or standards to be used in making decisions about the care to be provided to offenders. Guidelines submitted must be appropriate, responsible and reflect an understanding of the realities of providing health care to the offender population in Minnesota.

K. FIT TESTING

The CONTRACTOR shall ensure that appropriate CONTRACTOR personnel are "Fit Tested" so that medical care can be provided to offenders with communicable illnesses.

L. EMERGENCY MEDICAL CARE TO PERSONNEL, DEPARTMENT EMPLOYEES AND VISITORS

The CONTRACTOR shall provide but not be financially responsible for emergency medical care for all personnel and DOC employees in the event of accidents or incidents requiring emergency medical response. In addition, the CONTRACTOR is responsible for the emergency medical care provided to all visitors and any other persons on- site at the facilities. After the emergency, the CONTRACTOR may refer such personnel, DOC employees, and visitors and other persons to outside medical doctors or facilities, or to be followed by such persons' own physicians. The CONTRACTOR shall not be responsible for and shall not provide any routine health care for personnel, DOC staff, visitors or other persons on-site at the facilities.

M. THERAPEUTIC MEDICAL DIETS

The DOC offers a lacto-ovo alternative meal that meets the requirements of most medical diets. Practitioners shall consider the suitability of this option prior to ordering a special medical diet. Special medical diets shall be ordered and reviewed by a provider in consultation with the DOC dietitian as indicated. The DOC dietician will work with the food service managers to ensure special diets are provided. Nutritional supplements ordered by a practitioner will be paid for by the CONTRACTOR.

N. VISION CARE SERVICES

Routine Vision Care Services

Minnesota licensed optometrists shall be retained by the CONTRACTOR and shall offer routine vision care services within the facilities, to the extent possible based upon the availability of necessary equipment provided and maintained by the DOC.

Subsequent to an initial evaluation of routine vision care needs by an optometrist, based on nursing referral from the intake visual acuity screening, offenders will be afforded the opportunity to receive such services at intervals of no greater frequency than 2 years in accordance with guidelines of the American Optometric Association. Offenders 50 years of age or older and diabetic offenders will be afforded the opportunity to be examined by the optometrist at intervals of no greater frequency than annually.

In the event of identification of a special need which arose prior to the defined frequency intervals, such as a traumatic injury or a disease or disorder, which impacts vision, the offender may be evaluated by the optometrist more often than specified herein and referred to a physician based upon demonstrated clinical need.

Eyeglasses

Eyeglasses recommended by an optometrist for an offender shall be provided by the CONTRACTOR. Offenders in need of eyeglasses shall be provided with one pair of single vision or bifocal safety lenses (with lines) in a safety frame and lenses authorized by the DOC. Only offenders with an acuity value in either or both eyes above 20/40 shall be eligible for corrective eyeglasses. Exceptions may be granted only with the approval of the CONTRACTOR's medical department based on a recommendation from the treating optometrist.

Contact Lenses and Tinted Lenses

Contact lenses and tinted lenses will be provided by the CONTRACTOR only in response to a legitimate medical need (e.g., when the vision is not sufficiently correctable with eyeglasses to maintain routine function) as clinically determined and recommended by an ophthalmologist with the approval of the CONTRACTOR's utilization review department and the DOC.

Replacement

Replacement of eyeglasses or contact lenses provided by the CONTRACTOR shall not occur more frequently than the time intervals for re-evaluation by an optometrist. If the eyeglasses or contact lenses are lost or damaged due to negligence by the offender, the offender will be responsible for the cost of replacement. If the inmate is determined indigent by the DOC, the cost of replacement shall be made from the risk share. The CONTRACTOR may provide a replacement only when the need occurs through no fault of the offender and only with clinical necessity and authorization of the CONTRACTOR's medical department. Any exceptions to this must be approved by DOC.

O. PHARMACY

The CONTRACTOR shall provide all prescription pharmaceuticals for the offenders prescribed by the CONTRACTOR's personnel or eligible DOC health care staff. The CONTRACTOR must also arrange for back-

up pharmacy services if prescriptions must he started prior to when they can be obtained by the contract pharmacy. Cost for obtaining and delivery of back up pharmacy items is the CONTRACTOR's responsibility.

The CONTRACTOR shall provide a consulting pharmacist to visit each facility on a monthly basis for review of drug interactions, cost containment, drug disposal and assurance of quality control and regulatory compliance.

Reviews of non-formulary medication requests shall be made within 24 hours of such request or on the next business day.

Areas of concern or interest are identified through the Pharmaceutical & Therapeutics (P&T) Committee, Board of Pharmacy requirements, and DOC policies. The CONTRACTOR shall provide a consulting pharmacist to participate on the P &T committee.

The CONTRACTOR shall, during the first 3 months of the contract, meet all Minnesota Board of Pharmacy standards or work with the Board of Pharmacy to obtain any necessary and appropriate variances.

The CONTRACTOR shall provide reports on pharmacy utilization and prescribing practices as requested by the DOC.

The CONTRACTOR shall provide over the counter medication prescribed by the CONTRACTOR's personnel or eligible DOC health care staff. Prescribers shall comply with Division Directive 500.2011 Title: Over-the-Counter Medications (OTC).

Release Medications
CONTRACTOR shall ensure the following practice: At the time of release from a correctional facility, each offender is given a seven-day supply (or remainder of current prescription, whichever is greater) of medications unless otherwise restricted. Offenders must also receive written prescriptions for an additional thirty-day supply of medications where it is responsible to do so or as requested by the DOC. A thirty-day supply of psychotropic medications will be required for release medications for offenders with severe and persistent mental illness and those otherwise on neuroleptic medications. All prescribers must obtain a Medicaid provider number.

P. HEPATITIS C TREATMENT

The CONTRACTOR shall provide services for the diagnosis and treatment of Hepatitis C within the then current treatment guidelines and then current Hepatitis C treatment protocols established by the DOC, as incorporated herein by reference. This includes requirements to perform liver biopsies, lab tests, medications, and psychiatry, and may change from time-time, at the discretion of the DOC.

Q. OFFENDER SPECIFIC EQUIPMENT

The STATE shall be responsible for the cost of all durable medical equipment not otherwise addressed in this contract that is intended for use on multiple offenders over time. Durable medical equipment shall be defined as medical equipment that was designed for repeated use, can withstand repeated use; and is not disposable in nature.

The STATE shall be responsible for the cost of non-durable medical supplies and equipment used in the provision of offender health care in the normal operations of the clinics. Non-durable medical equipment shall he defined as medical equipment or supply that was designed for single use, not reusable, and disposable in nature.

The CONTRACTOR, through the risk share, shall be responsible for practitioner ordered medical prosthetics and medical equipment intended for an individual's personal use. This includes medically ordered purchases,

rental, or necessary repairs of artificial limbs, prosthetic eyes, custom wheelchairs, hearing aids, adaptive devices, specialized beds, and any other equipment specifically ordered for an individual. The possibility of use by another offender requiring similar or same custom-made medical equipment does not alter the status of the equipment as custom-made, so long as that equipment is intended for the immediate use by a specific offender or for a specific offender's health needs. Non-durable medical supplies such as accessories and attachments for durable medical equipment such as but not limited to roho cushions, and masks and tubing force-pap, bi-pap machines and physical therapy braces and splints will be the responsibility of the CONTRACTOR. Equipment provided by emergency rooms, hospitals or other off-site providers which meets utilization review criteria shall be funded from the risk share. Necessary repairs to an offender's personal prosthetic devices or equipment, such as wheelchairs shall be funded from the risk share as an alternative to replacing such property with new devices or equipment.

The CONTRACTOR shall be responsible for the cost of all other practitioner ordered medical equipment and supplies not herein defined, with same to be funded from the risk share. Should the CONTRACTOR and the STATE disagree on whether the equipment is the CONTRACTOR's or the STATE's responsibility, the CONTRACTOR's regional manager and the STATE's contract monitor will mutually determine who is responsible for the cost of such equipment.

R. CONTINUITY OF OPERATIONS PLANNING

The CONTRACTOR shall provide a comprehensive continuity of operations plan to the DOC prior to contract execution. This provision shall be consistent with MDOC Policy 105.012, *Continuity of Operations*; Division Directive 500.012.

S. DENTAL SERVICES

The CONTRACTOR shall provide dental services consistent with DOC policy on an as needed basis. From time to time, the DOC may have an emergent need for dental services due to unexpected vacancies in the STATE dentist positions. The CONTRACTOR may be asked to provide dental services at an additional cost to the STATE should this need arise and should the CONTRACTOR be able to recruit qualified dentists to provide these services.

T. PSYCHIATRIC SERVICES

The CONTRACTOR shall provide competent and appropriate psychiatric assessment and ongoing care at each facility for offenders. The CONTRACTOR may utilize a mixture of qualified primary care providers and psychiatric nurse practitioners and board certified or eligible psychiatrists in meeting the provider hour criteria per the ratios provided and attached to this contract. Initial psychiatric assessments and the ongoing care for especially complex psychiatric cases must be provided by board certified or eligible psychiatrists at all facilities. Routine and follow-up psychiatric care may be provided by non-psychiatrist providers

The percentage of psychiatric hours provided by non-psychiatrist providers is not to exceed 50% at any site. Because of the more challenging clinical environments at the MCF-OPH and MCF-SHK, the percentage of psychiatric service hours provided by non-psychiatrist providers is not to exceed 30%at these facilities. The percentage of psychiatric hours provided by non-psychiatrist providers (PC-PSY) at SCL and RW is not to exceed 40%. <u>These percentages may be revised upon written mutual agreement of both parties.</u>

The CONTRACTOR is responsible for demonstrating the competence of non- psychiatrist providers to perform psychiatric services to the satisfaction of the DOC. Documentation of specialized training and experience, interviews and performance monitoring are examples of how competence may be demonstrated. Exceptions to these percentages may be made with the approval of the DOC.

Some DOC facilities maintain chemical dependency and/or sex offender treatment in addition to mental health services (which are available at all sites). There is relatively high comorbidity between these disorders within the DOC. In order to competently address the more complex clinical needs presented by offenders with multiple disorders and to provide psychiatric support for the DOC's treatment integration plans, the CONTRACTOR shall ensure that at least one psychiatric provider has competence in the provision of psychiatric services with populations with mental health, chemical dependency and sex offending concerns. This provider is to be available to provide consultation at any of the DOC sites either in person or by telemedicine.

Telemedicine: The DOC may acquire the equipment and software needed to facilitate telemedicine among Central Office and each of the facilities during the duration of this contract. Related to psychiatric services, telemedicine will not be an acceptable option for routine psychiatric care. DOC telemedicine equipment, if available at some point during this contract, would be made available to the CONTRACTOR at no cost for the purpose of providing psychiatric care at DOC facilities, including; emergency psychiatric care, providing psychiatric coverage for a facility during brief periods agreed to by the DOC when no other practical options are available (i.e., interim coverage following the departure of a provider), or consultation on complex cases by a psychiatric provider with specialized expertise.

Teamwork and consultation: Psychiatric providers are considered part of treatment teams within the DOC and are expected to consult with medical, nursing, behavioral health and other DOC staff as needed to provide comprehensive treatment and continuity of care. It is expected that psychotropic medication will be prescribed based on verification of reported symptoms, summary file review, formal assessments provided by qualified DOC behavioral health staff relevant to the stated purpose of the referral. Psychiatric providers are expected to participate as requested in behavioral health and health services staffing meetings for the purpose of mutual consultation and education.

Productivity: Barring other barriers to the provision of treatment (i.e., facility lock-down), psychiatric providers are generally expected to meet productivity standards:
New Assessment: 40-45 minutes
Follow-up Assessment: 15-20 minutes
Chart Review: 5 minutes

Documentation: Providers are expected to dictate or write clinical notes and orders on the same day services are provided. Providers are expected to use SOAP note format for all follow-up assessment notes. Initial assessments shall minimally contain the following content areas:
Presenting problem
Current medications (if any)
Medication history
Psychiatric history
Current symptoms
Physical health
5 Axis Diagnoses
Summary
Plan
Referrals

U. ELECTRONIC HEALTH RECORDS

The DOC intends to begin utilizing an EHR to comply with state and federal mandates. The CONTRACTOR will be encouraged to provide input into the design and implementation stages of this project but will have no contractual obligation in this regard. The DOC will provide the CONTRACTOR's personnel training on any new

record keeping systems. The CONTRACTOR is expected to utilize the DOC EHR systems as it is implemented.

V. E-MAR

The DOC is currently using an electronic medication ordering and administration system utilizing bar code scanning technology. The CONTRACTOR shall provide a similar automated system.

W. AUDIOLOGY SERVICES

The CONTRACTOR shall provide the continuum of audiology services, including hearing tests, hearing aids, fitting, adjustments, repair and batteries.

X. SOFTWARE APPLICATIONS

The CONTRACTOR shall offer value added programs, as identified in its response, at no additional cost to the DOC. Programs that require no DOC resources to implement and use are authorized by this contract. Programs that require ongoing commitment of time or labor by DOC employees shall require written approval by the DOC prior to implementation. The DOC has full discretionary authority to refuse to allow implementation of any value added program. Examples of such programs are contained in the chart:

RFP Reference Examples	Identifier/Name	Description
Executive Summary, Section 2. A. On-Site Services	TruCare	Used to isolate and target offenders having unique risk characteristics, and to deliver specific care management programs for those offenders.
Executive Summary, Section 2. B. Ambulance Services	Centelligence	Analytics tool, which uses clinical, risk, and administrative profile information obtained from medical, pharmacy, and lab data to proactively identify offenders with high risk profiles that require clinical management in order to prevent or minimize future costs.
Executive Summary, Section 2. Q. Hepatitis C Treatment.	CentAccount	Monetary rewards to offenders for targeted healthy behaviors.
Executive Summary, Section 2. Q. Hepatitis C Treatment.	Nurtur	Provides flexible and customized programs for wellness, disease management, episodic/catastrophic care management consultation, life resource information, education and training materials, and consultation.
Executive Summary	Impact Pro	Allows identification of care opportunities by using a mix of rigorous proprietary algorithms, including risk stratification, identifying adverse trends and care gaps, and combining these algorithms with evidence based medicine guidelines.
Section 2. N. Therapeutic Medical Diets.	Nurtur Dietitians	Nutritional educational handouts and opportunities to help the offender population understand that dietary choices play a significant role in health outcomes. Provider and MDOC health care staff training resources and innovative ways to get the dietary message to the offender.
Section 2. W. E-Mar.	Sapphire Health eMAR	Electronic medication administration record

ATTACHMENT 2 - A

ADMINISTRATIVE SERVICES

The CONTRACTOR is responsible for addressing the following administrative requirements to ensure adequate coverage for the delivery of health care services and customer service. The CONTRACTOR must establish a system that blends its personnel and staff with the DOC staff (primarily nursing and psychology and dental) and include a process for issue resolution to respond to operating or coordination problems.

STAFFING

A. STAFFING MATRIX

The CONTRACTOR shall provide a staffing matrix clearly articulating the staffing necessary to provide the required services. In order to provide adequate and sufficient personnel to fulfill its obligations under this RFP, the CONTRACTOR shall recruit and retain, whether as employees, independent CONTRACTORs or otherwise, physicians, physician's assistants, nurse practitioners, occupational and physical therapists, ancillary providers, consultative and administrative personnel and such other personnel as the CONTRACTOR deems appropriate.

The CONTRACTOR shall complete a staffing plan that identifies the number and type of staff by shift that they will provide to meet the expectations of the RFP. If the DOC determines the approved staffing plan is inadequate in practice to meet the offender health care needs, the CONTRACTOR must modify the provider coverage to ensure that timely services are provided.

B. STAFFING LEVEL CHANGES

Staffing level changes as may be necessitated from time to time are to be determined by the mutual agreement of the CONTRACTOR and the DOC with the appropriate adjustments to compensation, if necessary. Such changes shall be implemented with the written approval of the DOC, and reflected by appropriate amendments to the contract, if necessary. Mutually agreed upon staffing level adjustments that do not require funding increases may be approved in writing by the DOC and do not require a contract amendment.

C. LICENSURE AND CREDENTIALING

The CONTRACTOR shall ensure that all personnel are currently licensed, certified, and/or registered to the extent required by the State of Minnesota and as necessary for the CONTRACTOR to fulfill its obligations under this contract. The DOC shall not bear financial responsibility for the cost of any required education to obtain or maintain such credentialing.

Physician Credentialing
The CONTRACTOR shall conduct credentialing of all personnel who are physicians, to the extent required by Minnesota law and other pertinent regulatory authorities, and must submit satisfactory evidence prior to the date that the physician commences the provision of services at a facility. The CONTRACTOR shall have a written policy and procedure regarding the physician credentialing process approved by the DOC. Each physician credential file shall contain, at a minimum, the following documents:

1. Copy of verified Minnesota license to practice medicine;
2. Copy of application for initial or renewal registration;
3. Copy of Federal controlled substance registration;
4. Evidence of malpractice insurance with claims and/or lawsuits pending or closed during the past ten years verified by the insurance carrier;

5. Copies of verified medical education documentation including medical school, internship, residency and fellowship programs;
6. Ten-year employment history, present and past, where the physician has practiced and reasons for change;
7. Evidence of reasonable inquiry into employment history with emphasis on assessment of clinical skills;
8. Evidence of recent TB testing and results;
9. Signed release of information form;
10. Information regarding any criminal proceedings;
11. A report from the National Practitioner Data Bank; and
12. Medicaid Provider number and NPI number.

A physician shall not commence services with the DOC while the full credentialing process continues or without evidence of a current Minnesota license to practice, evidence of current DEA registration, evidence of current TB testing, and evidence of current malpractice insurance at a minimum. Specialty clinic physicians, retained by the CONTRACTOR on a part time basis, who have privileges at a licensed Minnesota hospital may substitute documentation from said hospital if such documentation indicates conformance with Minnesota law.

Each physician shall be re-credentialed every two (2) years. All credential records, both for active and inactive physicians, shall be the property of the DOC, but shall be maintained by the CONTRACTOR at its corporate office and by the DOC Health Services Unit. A periodic audit of the credential files shall be conducted by a representative of the DOC. After the expiration or termination of the contract, the credentialing records will be given to the DOC and the CONTRACTOR shall have access to and may copy any such credentialing records.

The provisions of this section shall survive the termination or expiration of the contract.

Credentialing of Other Providers
Nursing Credentialing
All nursing personnel must have graduated from an accredited nursing program and hold applicable Minnesota licenses and advanced degrees. Nursing personnel shall not commence employment without evidence of a current Minnesota license to practice, evidence of current DEA licensure, where applicable, practice agreements with a Minnesota licensed physician, Medicaid number and NPI number, evidence of malpractice insurance coverage and evidence of current TB testing.

Ancillary Staff Credentialing
All other ancillary personnel, including but not limited to x-ray technicians, physical therapists, occupational therapists, phlebotomists, optometrists, podiatrists, infectious disease expert, and/or nursing assistants, must meet applicable Minnesota regulatory requirements and community certification training standards. Evidence of malpractice insurance coverage and current TB testing shall be provided.

D. SECURITY CLEARANCE

All contract personnel must receive security and background clearance by the DOC prior to provisions of services. This includes a criminal background check. The DOC will not unreasonably withhold or delay such clearance.

E. ORIENTATION

Personnel assigned to the facilities must participate in DOC sponsored orientation classes prior to providing services at a facility, and attend DOC training classes that, from time to time, may be reasonably

required. Part time personnel will attend orientation and training as determined by the DOC. The CONTRACTOR's regional office staff (regional medical director, manager and clerical) must attend the DOC orientation academy.

F. APPLICATION OF DEPARTMENT RULES

Contract personnel shall comply with all DOC policies and shall be subject to the rules and standards of conduct set forth in the DOC's policies.

G. HIRING AND FIRING AND SUBCONTRACTOR TERMINATION

The CONTRACTOR shall have the right to hire and fire or terminate the employees or subCONTRACTORs, except that the CONTRACTOR shall not employ for the purposes of carrying out its obligations under this contract any person who is simultaneously employed by the State of Minnesota or any agency thereof.

The DOC may deny entrance of any of the CONTRACTOR's personnel to any or all facilities. The DOC shall notify the CONTRACTOR's program/regional manager of such denial and the reasons therefore as soon as reasonably practicable.

If the DOC is dissatisfied with any personnel provided by the CONTRACTOR to provide services under the contract, the CONTRACTOR shall resolve the problem to the DOC's satisfaction, including replacement of the personnel within a reasonable amount of time. If necessary, the CONTRACTOR must supplement the position with appropriate temporary personnel until the CONTRACTOR can secure a permanent replacement.

H. REGIONAL MANAGER

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a regional manager.

I. STATEWIDE MEDICAL AND PSYCHIATRIC DIRECTOR

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a physician to act as Statewide Medical Director. The Medical Director must be licensed in Minnesota and Board Certified in one of the following: Internal Medicine, Family Practice, Surgery, Preventive Medicine, or Emergency Medicine.

The CONTRACTOR shall, with the approval of the DOC, which approval will not be unreasonably withheld or delayed, appoint a physician to act as Statewide Psychiatric Director. The Psychiatric Director must be licensed in Minnesota and Board Certified in psychiatry.

J. TRANSLATION SERVICES

The CONTRACTOR shall provide translation services, when required, to meet the needs of the offender population. Offenders cannot be utilized as translators.

K. COMPENSATION AND BENEFITS OF PERSONNEL

The CONTRACTOR shall have the responsibility for determining the compensation, terms and conditions of employment or engagement and benefits of, and for paying all compensation and other benefits to the personnel. Hourly rates of compensation for each category of personnel, including independent

CONTRACTORs, shall be submitted to the DOC on an annual basis. DOC staff may act as advisors to the CONTRACTOR in determining compensation and benefits. Annual increases, bonuses, moving expenses and/or any incentives provided to the CONTRACTOR's personnel must be approved by the DOC.

L. DEPARTMENT ACCESS TO PERSONNEL, PAYROLL, RECORDS AND UTILIZATION CLAIMS DATA

Upon reasonable prior notice, the DOC may review at the CONTRACTOR's offices the employment applications, resumes and personnel files of the personnel during regular business hours. At the request of the DOC, the CONTRACTOR shall provide a list of the names and home addresses and telephone numbers of all personnel.

The CONTRACTOR shall provide copies of subcontracts and payroll hours by facility each month.

M. MEDIA RELEASES

While the CONTRACTOR may be required by government regulation to make certain public disclosures, the CONTRACTOR or CONTRACTOR's personnel shall not issue press or media releases regarding the program, the DOC or the contract, except in coordination with designated staff in the DOC Commissioner's office, and pursuant to the terms of the Contract, DOC policies, and applicable law.

N. STAFF MEETINGS

The CONTRACTOR shall ensure that personnel attend all staff meetings as required by the mutual agreement of the CONTRACTOR's Regional Manager and the DOC, including, but not limited to: facility biweekly meetings, quality assurance, mortality reviews, risk management, peer review, Pharmaceutical & Therapeutics Committee and meetings pursuant to medical and professional staff organization bylaws and rules.

O. SERVICES FOR OTHERS

This RFP shall not prevent any personnel from providing or performing services for others, nor shall this contract in any way restrict the CONTRACTOR from using personnel to provide the services or any other services for others. No personnel providing direct care services to offenders at facilities shall work more than one full- time equivalent, i.e., 40 hours per week, with the exception of the physician who is on-call for the system. Compensation for this responsibility is determined by the CONTRACTOR. The clinic hours at each site vary. However, the personnel must provide hours of services during the regularly scheduled clinic hours.

P. REGIONAL OFFICE

The CONTRACTOR shall establish and maintain a corporate office in the greater Twin Cities metropolitan area sufficient to meet contractual obligations if the CONTRACTOR is providing multiple services at multiple sites or if the DOC believes that it is in its best interest to have regional staff. Regional office staffing shall include, at least, the following positions and program functions:

1. One regional manager;	1.0
2. One statewide medical director;	1.0
3. One psychiatric director,	.6
4. Two schedulers,	2.0
5. One utilization management nurse,	1.0
6. One CQI/special projects nurse,	1.0
7. One office manager	1.0

The credentials of all regional office management staff shall be submitted by the CONTRACTOR to the DOC, and approved in writing by the DOC, prior to January 1, 2014 and thereafter whenever a vacancy in said staff shall occur.

Q. ON-CALL COVERAGE

The CONTRACTOR shall designate a physician for on-call to include house call services for the system 24 hours per day, 7 days per week. The CONTRACTOR shall provide the DOC monthly on-call schedules in advance of the month if more than one physician will be on-call. The on-call physician is expected to respond within 15 minutes. Treatment for injuries requiring suturing and/or minor surgical procedures shall be provided on-site when possible. House call and call back services may be implemented to eliminate off-hour ER visits more appropriately handled at the facilities.

The CONTRACTOR shall provide an additional level of on-call psychiatric coverage 24 hours a day, 7 days a week. Our psychiatric on-call coverage will be available to each facility and enable facility-based staff to obtain direct and rapid after-hours resolution to behavioral and psychiatric crises. Psychiatric on-call coverage schedules will be posted and distributed as part of physician on-call coverage schedules to ensure that nursing and other DOC staff has a single on-call provider schedule.

All services provided under this section must be performed by local Minnesota licensed providers with knowledge and experience in Minnesota's correctional environment.

R. HOURS OF WORK

Clinic hours will be provided between 0730 and 1600 hours; Monday through Friday on non-State holidays at all sites. Employees shall be scheduled to provide services during that time period. Practitioners shall work to coordinate their hours of service with the employees and DOC personnel and in accordance with the availability of the inmates. Patient lists and work load shall be monitored by the site Health Services Administrator to allow practitioners to complete all daily work within the specified time.

Practitioners who are scheduled for a full shift shall receive an unpaid 30-minute lunch break and two paid fifteen-minute break periods. Practitioners, at their option, shall be permitted to take the full sixty minutes of time during the lunch hour.

Practitioners will be permitted to provide services outside of clinic hours only in cases of medical emergencies, or by exception at the request of the DOC and with written authorization of the contract monitor.

The CONTRACTOR will be responsible for providing a time-keeping system acceptable to the DOC and ensuring that all contract practitioners document their times of arrival and departure using this system.

Practitioners will be compensated for on-call duty and for reporting in during off-duty hours to provide medical care

MINNESOTA DEPARTMENT OF CORRECTIONS

Central Office
1450 Energy Park Drive • St. Paul, MN 55108
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www.doc.state.mn.us

July 12, 2015

Peter Nickitas
Peter Nickitas Law Office
431 S. 7th Street, Suite 2446
P.O. Box 15221
Minneapolis, MN 55415-0221

Re: Barry Michaelson 203279

Dear Mr. Nickitas:

I am in receipt of your letter to me, dated June 26, 2015, through which Mr. Michaelson is requesting that Sovaldi be prescribed for treatment of his medical condition.

Your submission is clear, and complete, from my perspective, and complies with MN DOC policy 303.1001.

I am not a medical doctor and am therefore not licensed to prescribe medications or to direct the prescribing practices of licensed prescribing practitioners.

I have discussed Mr. Michaelson's request with Dr. David Paulson. I am advised that Mr. Michaelson does not currently meet DOC guidelines for anti-viral treatment; therefore I am denying his request at this time.

Sincerely,

Nanette Larson – Director
Health Services

Copy: Correspondence file

STATE OF MINNESOTA
Department of Corrections

DATE & TIME	
12 May 2015	FIB-4 score 1.39 - Low. Indicates Low risk for Fibrosis. Does not meet DOC guidelines for further evaluation & antiviral treatment. Should be monitored every 12 months. Note from Dr. Paulson email 20 May 2015. DMQ

EXHIBIT
#3
(3-11-16) CW

PENGAD 800-631-6989

OID

203279 9/16/1964

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Consult MCF-STW MICHAELSON, BARRY OID#: 203279 March 06, 2015
CHIEF COMPLAINT: Hepatitis C.
SUBJECTIVE: Today he wants an update of the DOC policy. The policy is not yet available for review. He expresses frustration in regards to his lack of treatment for hepatitis C. He does have hepatitis C type 1B. His last viral load was documented in 2010. He did have recent laboratory done that he wants reviewed today. He complains of symptoms long-term of bloating and dizziness which he states are due to the hepatitis infection.
OBJECTIVE: His laboratory dated 02/04/2015 shows AST 62, ALT 95, GGTP 124. His CBC was normal. Further review of the chart shows that he had an elevated blood iron in May of 2013 at a value of 180. Chart was reviewed. Discussion ensued. Total time 20 minutes.
ASSESSMENT: 1. Hepatitis C. 2. GI complaints of bloating.
PLAN: We will update his laboratory further. He insists that he needs B12 supplementation for his "healthy liver". I will obtain a B12 level, TSH, serum iron, and ferritin. I will also do a hepatitis C quantitative. We will notify him of these results.
Darryl Quiram, MD/0977 D: 03/06/2015 09:20:51 T: 03/07/2015 JOB#: 371668
Dictated, but not Reviewed

3-16-15
Name Michaelson, Barry OID 203279 1 MO F/U labs
WT T P R SPO2
B/P R L ARM
Signature Date/Time
Ck labs not back – R/S next week RF

3/26/15
Name Michaelson, B OID 203279 f/u lab results
WT 238 T 97 P 114 R 16 SPO2 96% also Pain R/T
B/P (R) L ARM 156/100 Pain Level: 0-10 7-8/10 tooth back molar
Signature O. [illegible] RN Date/Time 3/26/15 top (R)
411260
Toradol
{[illegible]}

Consult MCF-STW MICHAELSON, BARRY OID#: 203279 March 26, 2015
CHIEF COMPLAINT: Tooth pain and follow up laboratory.
SUBJECTIVE: His hepatitis C RNA returned at 128,000, which is about the same as his previous. His serum ferritin returned normal at 244. His vitamin B12 was normal at 357. His TSH was normal at 2.4. He is concerned today about his blood pressure, which is 156/100.
OBJECTIVE: He has tooth pain on the right which was recently treated by the dentist and now he is having severe pain. He wants to be seen back by the dentist. The chart was reviewed. Discussion ensued. Total time 10 minutes.
ASSESSMENT: 1. Active hepatitis C infection. 2. Labile hypertension.
PLAN: Advised that he restrict salt. I gave him a long-term recommendation weight loss, to build muscle mass and reduce his total caloric intake. In regards to his blood pressure, he should reduce his salt intake. We will do a weekly blood pressure check x4 and have him return to clinic in a month. He will have further evaluation of his hypertension with a urinalysis and a basic metabolic profile.
Darryl Quiram, MD/0914 D: 03/26/2015 09:41:42 T: 03/26/2015 JOB#: 411260
2032 Dictated, but not Reviewed

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

5070020045 MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Consult MCF-FRB MICHAELSON, BARRY OID#: 203279 December 02, 2014
SUBJECTIVE: Mr. Michaelson scraped his left temple on an ice chest, sustained a superficial laceration measuring about 4 cm in length. It does not gape at all, bleeds minimally. The edges come together easily with pressure and it is not deep. It involves only the epidermis. The area was cleaned with normal saline, dried. Tincture of benzoin was placed and wound edges were drawn together and Steri-Strips were applied. Patient was advised to keep the Steri-Strips in place for 48-72 hours and then they could be removed.
ASSESSMENT: Superficial laceration.
PLAN: Treatment as above.
Rolf Hanson, MD/0906 D: 12/02/2014 15:51:28 T: 12/03/2014 JOB#: 611666
Dictated, but not Reviewed

1-30-15 1235.
Name Michaelson, B. OID 203279
WT 238 T 97.1 P 99. R 16 SPO2 96%. Hep C tx, DD
B/P R (L) ARM 141/90. 1235.
Signature RFields CMA Date/Time 1-30-15

Consult MCF-STW MICHAELSON, BARRY OID#: 203279 January 30, 2015
CHIEF COMPLAINT: Hepatitis C.
SUBJECTIVE: This is a new patient to myself. He presents today angry. He is demanding to be treated for hepatitis C. He is threatening litigation. He references a requirement of chemical dependency preablation. States that he has completed this as an outpatient and it does not apply to him. Review of the chart shows that he has hepatitis C genotype 1 diagnosed in 2010. He had a viral load of 206,000 at that time. He today wanted a statement from me that I denying him treatment. I did inform him about the new policy changes of hepatitis C treatment that the Department of Corrections is finalizing. I referenced him to the central office for any further questions about it, but that I would be happy to review with him the guidelines. It was my understanding that within the next 30 days they should be published.
OBJECTIVE: Review of the chart shows his last laboratory was 07/2013 with a basic metabolic profile being essentially normal. He did have liver function last tested 05/2013 with a borderline elevated ALT of 69, borderline elevated AST of 44.
ASSESSMENT: Active hepatitis C with mild liver involvement.
PLAN: Will await the DOC guidelines and review with him in the future if he is a candidate or not for hepatitis C treatment based on new guidelines.
Darryl Quiram, MD/0906 D: 01/30/2015 12:58:14 T: 02/01/2015 JOB#: 752314
Dictated, but not Reviewed

3-6-15 0855.
Name Michaelson, B. OID 203279
WT 238 T 97.3 P 111 R 16 SPO2 95%
B/P R (L) ARM 155/89.
Signature RFields CMA Date/Time 3-5-15
F/up Hep C Quantitative
9/2010 sent 1B
Iron -180 (5/2017) 10/11/2016
Symptoms: dizzy, Bloating
321608

OID

03279 9/16/1964
MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES
MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Progress Note MCF-STW MICHAELSON, Barry OID#203279 09/26/2013

S: Reports that he has a 10 or so day history of loose stools associated with some diaphoresis and abdominal cramping. Almost all of which has fully resolved and today he says he has had only one normal firm stool. The only treatment he has had in the interim is clear liquid diet and he feels much improved at this time and has no abdominal discomfort at all. Past medical history is negative for significant pathologies. No hospitalizations or operations.

O: Objective exam shows a healthy-appearing middle-aged man whose vital signs are normal. Abdomen is soft and nontender anywhere and his pulse is normal.

A: Analysis is acute enteritis over the past two weeks, which is now nearly fully resolved.

P: No further treatment is indicated at this time. Follow-up p.r.n. should he develop any blood in his stools.

James Wischer, M.D./issv/7078/Dictated, but not reviewed

D/T Dictated: 09/26/13 14:45

7-25-14 BP (L) arm 144/91 P 113 R 22 T 97.9 O2 98%
09:45

Progress Note MCF-STW MICHAELSON, Barry OID#203279 07/25/2014

DOB: 09/16/1964

CC: Mouth pain.

S: This patient was in an altercation. He sustained a laceration in his mouth and is concerned about his teeth.

O: He has a 1-cm superficial laceration in the buccal mucosa of the lower lip. It is shallow. His two front teeth are in the upper, slightly loose to examination. He has no other significant injury with the exception of mild bruising of his gum line.

A: 1. Small laceration in his mouth.
2. Loosened teeth.

P: 1. We will refer to Dental as soon as possible. We will place him on a full liquid diet for a week.
2. He is advised to observe this laceration injury and that it should heal rapidly in his mouth.
3. He should return in the interim if there are any further concerns.

Darryl Quiram, M.D./isga/2725/Dictated, but not reviewed

D/T Dictated: 07/25/14 11:00

Name Michaelson OID# 203279 WT 235 T 97.9 P 95 R 20 SPO2 95%

B/P R (L) Arm 147/101 Pain Level: 0-10 0 Signature Q. Ekm 4w Date/Time 12/2/14 1585

(L) Forhead Injury

4166

203279 9/16/1964 OID

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Progress Note MCF-STW MICHAELSON, Barry OID#203279 06/07/2013

S: A middle-aged gentleman presents with concerns regarding his medications, intermittent blurred vision, and his recent lab tests.

1. Medications. Subjectively, he has been prescribed venlafaxine. On his last psych visit that was supposedly increased to 300 mg a day. The PharmaCore people here state that the XR form of it to be given h.s. max is at 225 a day and the number that is available for prisoners. This is somewhat different formulation from what he has had before in the past, although he has taken 300 mg of the regular release before, the XR form has different kinetics.
   O: Exam shows him to be somewhat agitated, but conversant and able to understand the pharmacology especially when it is pulled up and shown him on a screen that that is the company's maximal safe dosage.
2. Recent chemistries document that he had an elevated blood sugar in the 130s after he had milk and cookies and other sweets prior to coming to the medical department. He has put on about 40 to 50 pounds. Says he has intermittent blurring of vision in the left eye that fully resolves from time-to-time.
   O: Exam shows him to be alert and oriented. Vision is normal bilaterally.
3. Lab studies show that he has a depressed phosphate at 1.5. This presumably can be addressed with a multivitamin with minerals.
4. Chronic hepatitis C issues. His LFTs are only minimally elevated and it may be a subsequent to the hepatitis C, but certainly there is so little elevation that he is not at risk of developing cirrhosis just from this issue. Plan is for him to address the issue in several years when treatment has improved and it generates much less toxicity, as there is no evidence that early treatment decreases the rate of hepatocellular carcinoma.

A/P: Analysis:

1. Posttraumatic stress with patient who needs venlafaxine XR 225 h.s. and this will be arranged for him to KOP.
2. Diabetes, which is dietary induced. He is encouraged to lose some weight, change his eating habits, and we will arrange for follow-up.
3. Long-term history of hepatitis C with minimal expression for this. Follow-up will be in one month after an A1c is obtained and his dietary habits have changed.

James Wischer, M.D./iscm/3257/Dictated, but not reviewed

D/T Dictated: 06/07/13 11:33

Ht 5'7"

9/26/13 Name Michaelson, Barry OID# 203279 WT 330 T 97.3 P 81 R 16 SPO2 96 80

B/P R (L) Arm 126/87 Pain Level: 0- 10 ↓ Signature D. Culwick Date/Time 9/26/13 (1320)

Flu Continued diarrhea — S Culwick

7078

OID

203279 9/16/1964

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Progress Note MCF-STW MICHAELSON, Barry OID#203279 05/24/2013

S: Mr. Michaelson presents today for an evaluation. This gentleman I am seeing to discuss his medication issues and see if indeed there is any way we can help him. He has posttraumatic stress disorder as a result of abuse as a child. He is currently utilizing Effexor extended release, has been on 300 mg twice daily, however they have reduced it to 225 mg daily as a result of recommendations from PharmaCore. There have been a number of pharmacy problems and poor communication issues that have prevented him from actually receiving his medication on a routine basis. He notes that other than having some intermittent problems with depression and anger he feels that overall he has been able to tolerate it without too much discomfort. He does have his medications with him today.

O: On examination today he is alert, perhaps mildly depressed appearing white male, non-tangential in thought, anxious, questionably angry. Blood pressure is 146/93, pulse 102, respirations 20, temperature 99. Laboratory studies do show in the past, in 2010, he was hypothyroid with a TSH of 5.5, he has not had recent laboratory workup to include fasting lipid panel.

A: Impression:

1. Medication problems on Effexor. The patient having some issues with depression intermittently.
2. History of PTSD.
3. Please see attached psychiatric evaluation.
4. Possible hypothyroidism.

P: CBC, CMP, fasting lipid panel, TSH, Free T3 and Total T4. He will be followed up in two weeks, we will review all of those items. He is to continue his medications at least Effexor-R 225 mg daily. He will be followed up after his labs. I noted to this individual I will attempt to see if 300 mg twice a daily of Effexor was not unreasonable. However, PharmaCore prevents that, so keep him on his continued medication in accordance to Psychiatry.

Mark D. Zimmerman, D.O./uh/1831/Dictated, but not reviewed
D/T Dictated: 05/24/2013 16:55:25

6-6-13 | CMP, Repeated blood sugar 132 - will repeat & do Hgb A1C

Name Michaelson, B OID# 203279 WT 215 T 97.4 P 94 R 16 SPO2 98

B/P R (L) Arm 122/73 Pain Level: 0- 10 ____ Signature [illegible] LPN Date/Time 6/7/13 0920A

3257

NAME _____ OID _____

PRACTITIONERS NOTES

5070020045

MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME	
10/9/12 0850	Wt. 217 T. 97.6 P. 102 R. 16 B/P 134/7
	Dictated 0850 5236 — [signature]

Progress Note MCF-STW MICHAELSON, Barry OID#203279 10/09/2012

S: The patient is being seen today for hepatitis C information. The patient informed the provider that he would like some information about hepatitis C, and that he has been denied treatment because he is a drug and alcohol treatment mandate. He is asking for the policy number on that. Did inform the patient that the provider does not have the policy number for that. Did provide the patient with the Minnesota Department of Corrections Health Service Unit information and consent for evaluation and treatment of hepatitis C. Did review the six areas on the form and pointed out that after one or two criteria, satisfactory completion of chemical dependency treatment is a criteria. The patient requested that the provider sign a form saying that I was denying him treatment. Explained to the patient that I would not be denying him treatment, and that here is the policy. The patient states that he wants this policy in writing. Referred the patient to the DOC as he needs to fill up the evaluation form, then I can do my part and move that forward to the Department of Corrections for the eligibility checklist. The patient declined to sign the form as he said his family members have told him not to sign any forms. I will not able to move forward in completing the treatment eligibility checklist as this is a requirement on the checklist, _____ the patient. Once again the patient is requesting written documentation that he has been denied treatment by Health Services, and this provider did not provide him with that documentation.
Ann McDonald, NP/iscm/5236/Dictated, but not reviewed

5/24/13	S Flu injury report
1532	O 215 lb 99.1/102/20 146/93 SpO2 97% RA [signature]
	1831

03279 9/16/1964 OID

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME	
10.22.10 1030	WT 198 TEMP 97.1 BP 121/82 P 81 R 18 By F/U US of abdomen

Progress Note MCF-STW **MICHAELSON, Barry** **OID#203279** **10/22/2010**

S: The patient returns to clinic today for a follow-up on an ultrasound of the abdomen, which was ordered to assess for possible gallbladder stones. The report of the ultrasound shows that he does have gallstones without gallbladder wall thickening with the impression being cholelithiasis with possible cholecystitis, prominence of the spleen and possible fatty infiltration. The patient continues to complain of bloating and recurrent right upper quadrant pains. Given the ultrasound report that he has cholelithiasis with only possibility of cholecystitis I think at this time it would be prudent to refer him to gastroenterologist to evaluate whether he should proceed with a cholecystectomy.

A: Cholelithiasis with possible cholecystitis because of a positive Murphy sign, possible fatty infiltration of the liver, prominence of the spleen, hepatitis C genotype I with a viral load of 206,000 International Units per milliliter.

P: Offsite referral to gastroenterology for evaluation of the cholelithiasis with possible cholecystitis and continued symptoms.

Stanley Quanbeck, M.D./ss/8807/Dictated, but not reviewed.

8/10/11	Note dictated 1254 Ellerbusch CNP

Progress Note MCF-STW **MICHAELSON, Barry** **OID#203279** **08/10/2011**

S: The patient came to the Health Services. He evidently came from one of the shops and he had cut his left forearm approximately 3 inches above the wrist on the medial side. He evidently was lifting and caught his arm on an uncovered metal pipe causing a three-cornered tear in his skin. This will not stop bleeding. It has been bleeding quite a bit. The area was cleansed using Hibiclens and sterile water. The patient agreed to have sutures placed. Using sterile technique, the area was cleansed. Using 1% Xylocaine in a Tuberculin syringe, the area was injected. Using 4-0 Ethilon suture, four interrupted sutures were placed to close the laceration. The patient's tetanus diphtheria booster is current as of 2007. The patient was given Band-Aids to keep the area covered and that we would have him return in 10 days for suture removal. The patient did sign an approval to have the suturing done.

Judy Ellerbusch, CNP/isjr/1254/Dictated, but not reviewed

8.23.11 0905	WT TEMP BP P R 10d RTC - F/u suture remove. — Attested (PA) I'm req cancel of appt. I'm removed sutures himself, stating "My mom told me to + She's a doctor." I'm advised the wound needs to be seen for proper healing. Four pinpoint O/As noted along wound, which were scabbed. Ø S/Sx inf. Conferred c NP. Ø need to be seen. — Attested (PA)

203279 9/16/1964 OID

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

8/30/10 1040 WT 200 TEMP ___ BP 119/81 P 71 R 16

↑ Lft's

A: Hep B (+) - pt not aware had done IV drugs in Florida in the '80's; Had discontinued Risperdal, but now wants to go back on Risperdal

A: Hep A/B (+); ↑ LFT

P: Hep viral load & genotype
Referral to psych ASAP
120/73

9/3/10 1335 WT 203 TEMP 98.3 BP 120/73 P 81 R 14

Progress Note MCF-STW **MICHAELSON, Barry Scott** **OID#203279** **09/03/2010**

S: The patient returns to clinic today for a follow-up on recent blood draw, which was for hepatitis C viral load and genotype. This blood draw was apparently done two days ago and the results have not yet been returned. Thus the patient is informed that he will be called again to clinic when the results have come in.
Stanley Quanbeck, M.D./Rrp/3270/Dictated, but not reviewed.

9-23-10. 1045. WT 200 BP 120/82 P 97 R 16. HX) Flu Hep C.

Progress Note MCF-STW **MICHAELSON, Barry Scott** **OID#203279** **09/23/2010**

S: The patient has returned for a follow-up on hepatitis C and that he was previously informed that the HCV antibody test was positive. This was followed with a HCV viral load and genotype, and he is now informed that the HCV viral load is in fact active with a count of 206,000 International Units per mL and that his type is 1B. The patient reports today that he is now beginning to have pain in the right upper quadrant with bloating and occasional pain into the right shoulder. He states that he has been reading up on hepatitis C and has been reading up on the various symptoms that may be associated with hepatitis C. He notes that before he had been told that he had hepatitis C, he had had no such complaints.

A: Hepatitis C with active viral load and type I genotype. Recent right upper quadrant pain.

P: Ultrasound of the liver and gallbladder to assess for possible gallbladder disease but more likely this is psychosomatic given his reading of possible symptoms of hepatitis C. Referral to nurse practitioner, Mariam for follow-up of the hepatitis C and as much as this patient is desirous of going ahead with treatment if possible.
Stanley Quanbeck, M.D./ss/5455/Dictated, but not reviewed.

STATE OF MINNESOTA
Department of Corrections

DATE & TIME

Progress Note MCF-FRB **MICHAELSON, Barry** **OID#203279** **05/17/2010**

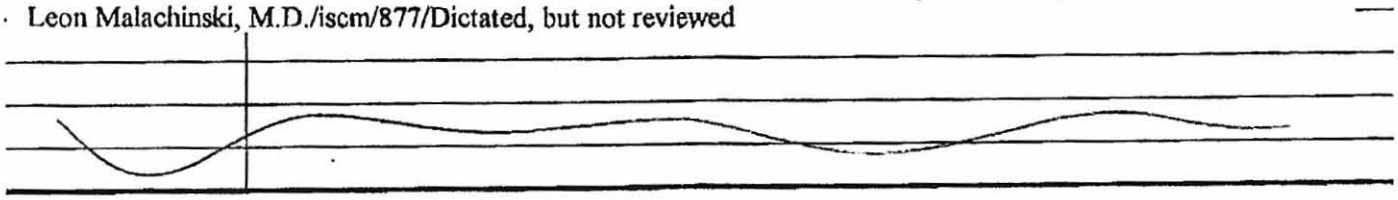
S: Mr. Michaelson presents today with a complaint of something happening inside his chest. He has difficulty explaining exactly what it is. He started up by saying it is a flutter, but then he says NO RUNNY He said that it is episodic. There is some precordial pressure associated with it. This has been going on for approximately two months. He says that this lasts for about three seconds, that there is no shortness of breath. No nausea or vomiting. No sweating. No radiation, he only notices it when he is lying down. If he gets up and moves around, it goes away immediately, so he has relief with exercise. This has been going on like he said for two months. An EKG was performed, which showed a normal sinus rhythm and a normal EKG. He denies any seizures or cephalgia. Denies any diplopia, photophobia, scotomata, blurred vision or loss of vision. Denies otalgia, otorrhea, tinnitus or deafness. Denies rhinitis, rhinorrhea, epistaxis or anosmia. Denies dysphagia, dysphonia, dysarthria, orodynia or loss of taste. Denies radiation into the neck, back, jaw or upper extremities. Denies any weakness associated with this sensation. He denies PND, orthopnea, exertional dyspnea, cough, chronic cough, productive cough, hemoptysis or night sweats. Denies nausea, vomiting, constipation, diarrhea, melena, hematemesis, hematochezia or abdominal pain. Does admit to occasional problems when he has a hard stool. He thinks he does have a hemorrhoid and that irritates him. He denies any dysuria, hematuria, pyuria, frequency, urgency, polyuria, or flank pain. He denies any urethral discharge. Denies any paresis, paralysis or paresthesias.

O: Physical exam revealed 5-foot 7-inch and 201-pound Caucasian male well oriented in all spheres, well nourished, well developed, in no acute distress at this time. Blood pressure 107/68, pulse 66, temperature 98.7, and O2 sat 95%. Head: Normocephalic. He has a couple of scars on his right superior temporal area of the scalp. This was as a result of an encounter with an ~~eye~~ I beam while he was working in construction. Some sutures were placed and he said he never lost consciousness and did not have any further injury. No sequelae associated with that. Eyes: EOMI, PERLA. CD ratio of 0.3. AV ratio of 2 to 3 without hemorrhages, exudates, or nicking. TMs clear bilaterally. Good cones of light. No fluid is noted. No masses or discharge seen. Nares are patent bilaterally. Good nasal mucosa. No rhinitis, rhinorrhea, or epistaxis. There is no turbinate hypertrophy. No septal lesion or deviation or masses are seen. Mouth: Teeth in fair repair. Tongue without lesion or deviation. Posterior pharynx is normal. Uvula without lesion or deviation. No oral masses are seen. No carotid adenopathy is palpable. Carotids are +2 bilaterally without murmur, without bruits. Heart: Regular rate and rhythm without murmur, S3, S4. Lungs: Clear to auscultation without adventitious sounds. No abnormal palpations are noted in the chest. There is no thrill and no arrhythmia is noted upon extensive auscultation. Good bowel sounds in all quadrants. There is no organomegaly. There is no tenderness to light or deep palpation. Femoral arteries are +2 bilaterally. There is a negative rebound and negative McBurney. DTRs are +2 bilaterally biceps, triceps, brachioradialis, Achilles, and patellar. Cranial nerves II through XII are intact bilaterally. Dorsalis pedis and posterior tibial pulses are +2 bilaterally additionally. His muscular strength is preserved. His grip strength is 5/5. His shoulders, biceps, triceps, and brachioradialis are all +5/5 and equal bilaterally. There is no gait dysfunction and there is no adiadochokinesia.

A: Assessment at this time is probable palpitations.

P: I have ordered a CBC and a thyroid profile. I am ordering a CMP too and we will get a thyroid profile and UA. There is no medication now. He should continue on his medications as prescribed by Dr. Hardrict.

Leon Malachinski, M.D./iscm/877/Dictated, but not reviewed



NAME _____ OID _____

PRACTITIONERS NOTES

STATE OF MINNESOTA
Department of Corrections

DATE & TIME	
10/26/09	Intake PE
	- requests Lab + PE info from Anoka Cty
	(ROI done) └ rectal → F/u.
	- Hx of tinnitus R+ > Lt (exposure to loud noise)
	exam w/in nml limits.
	- c/o pain in knees + shoulders. Probable
	arthritic changes due to occupation.
	advised gentle exercise + NSAIDs
10/28/09	Records rec'd Anoka Cty Jail ——— C. Moss, MD
10/30/09	Old DOC chart reviewed ——— C. Moss, MD

OID 0825 NAME

Date/Time 11.9.09 Wt 201.6 BP 107/66 P 65 R 20 T 97.0 Nurse [illegible] RN

	Review of labs rec'd from Anoka Cty — C. Moss, MD
5-17-10	T-98.7 P 66 BP 107/65, SaO2 95% [illegible] RN
	Offender reports Dr. [illegible] referred from Psy. [illegible]
	2 mos also "flutter" in chest — episodic. [illegible] 3/25.
	(-) SOB (-) N/V. (+) precordial pressure [illegible] 3 sec) (-) diaph.
	(-) radiation, [illegible] exercise. Happen c lying down.
	A) Palpitations P) [illegible]
	Obesity No Rx now
	[signature]

OID

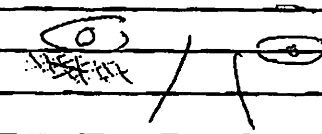
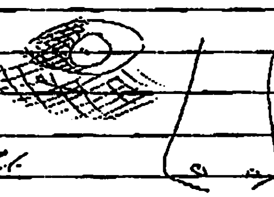
203279 9/16/1964

MICHAELSON, BARRY SCOTT

PRACTITIONERS NOTES

MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE / TIME	
10/29/07 12:11 AM	(S) Inmate says he was assaulted & got cut wound below Rt eye.
	(O): He has about 15 mm oblique cut wound at below Rt eye surrounded by bruised area. There is a persistent mild bleeding from lat side of the wound. 
	(A) Cut wound below Rt eye
	(P) area prepped & draped c̄ Iodine and Alcohol in the usual way, the wound was infiltrated c̄ 5cc of 1% Lidocaine. 5 stitches of 6-0 were taken to close the wound. As I noticed persistent bleeding from lat side of the wound I took another extra stitch - Pt tolerated procedure well. MD.
10/29/07 10:34 AM	(S) F/U Rt eye injury C/O pain.
	(O) Rt eye Pupil 4mm, regular shape and reaction to light, equal to Lt pupil. There is Rt sub conjunctival hge and swelling, bluish discoloration right below Rt eye. No Hyphema. 
	(A) S/P assault & sutured cut wound below Rt eye
	(P) Will add Triple AB ophthalmic oint to Rt eye BID x one week. F/U for one week.
10/29/07 10:40 AM	He C/O of having 2 loose teeth as he claimed a C/O put pressure c̄ his knees on it. O/E he has slightly loose two incisors in his lower mandible. I called the Dentist who had a look on it & recommended to avoid putting pressure on these teeth. MD.

NAME ______________________ OID ____________

STATE OF MINNESOTA
Department of Corrections

DATE	
7/29 [illegible]	**Medical Consult MCF-SCL** MICHAELSON, Barry OID#: 203279 July 28, 2006
	S: The patient comes in followup of constipation; please see previous notes. Essentially, the patient is improved today, ate two meals yesterday and breakfast this morning; no vomiting. He had a stool yesterday after an enema and mag citrate. It took a second enema of tap water, using the same container, but did not get much result from that. He still had some abdominal cramping and pain last night but, again, no vomiting.
	O: Abdomen was soft, somewhat tender in that right upper quadrant, but certainly no rebound and no masses.
	A: Abdominal pain with constipation, resolving.
	P: As the patient has improved gradually over the last two days, we will give him Milk of Magnesia today for Saturday and for Sunday, and he already has an appointment scheduled back for Monday; he will follow up at that time.
	Keith Krueger, MD/mt5
	D: 07/28/06 T: 07/28/06 JOB#: 9347
	Dictated, but not reviewed
7/3	**Medical Consult MCF-SCL** MICHAELSON, Barry OID#: 203279 July 31, 2006
	S: The patient comes in today for followup of constipation. Please see previous dictation from 07/26/06, 07/27/06 and 07/28/06. Dr. Krueger saw him in my absence on 07/28/06 and gave him Milk of Magnesia to take over the weekend. He says he is much better, but he did eat light meals over the weekend and tried to drink a lot of fluids. He still has been having some diarrhea and stools are not back to normal yet. He is not having the abdominal pain as he was previously. He has been trying to drink lots of fluids.
	O: No exam is done today.
	A: Constipation.
	P: We will have him use Dulcolax pads one q.d. and Milk of Magnesia on a p.r.n. basis. We will schedule him back in one month for followup.
	Imo Powell, R.N., C.N.P./mt7
	D: 07/31/06 T: 07/31/06 JOB#: 9481
	Dictated, but not reviewed
	8/18/06 Psychiatrist Appt. see dictated note [initials]
8/30/06	1025 - MD appt: abd. pain. 97.7 - 80 - 18 - 110/68 - wt 300 [signature]
	(S) C/o of Abd. cramping - Move his bowel everyday but he thinks he is constipated
	(O) Abd. lax. [illegible] - No organomegaly
	[illegible] exam is [illegible]
	Ap Functional dyspepsia - will recommend bland diet -
	? IBS → will put on fiber
	[signature]
	1/5/07 Psychiatrist Appt. see dictated note [initials]
	3/30/07 Psychiatrist Appt. see dictated note [initials]

NAME OID

3070020045 PRACTITIONER NOTES MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE **Medical Consult MCF-SCL** **MICHAELSON, Barry** **OID#: 203279** **July 26, 2006**

7/6 **S:** The patient is down here today for sick call. He said that he is having some abdominal pain and cramping since the morning of 07/24/06. He said, initially, it was just some mild discomfort, cramping, especially on the upper and lower right abdomen. He said he has not had any fevers or chills with this. He has felt a little bit of nausea but no vomiting. He said the pain worsened over yesterday, and he is having sharp, stabbing pain that comes and goes. He denies having any dysuria, no constipation or diarrhea, though he said that he has not had a bowel movement for a couple of days. Prior to that, he was going what looked like just little marbles. No black or bloody stools.

FH: Unremarkable.

PMH: No history of abdominal surgeries.

CM: Wellbutrin and Celexa.

ROS: Otherwise negative.

Allergies: Penicillin.

O: Blood pressure is 162/91, temperature 98.3°, pulse 81, respirations 20. He was a little diaphoretic when he first came in and saw nursing staff, but when I saw him he was better. Heart rate is regular. Lungs are clear. Abdomen is obese. Bowel sounds are hypoactive but not tympanic. I did not hear any significant bowel sounds in the left upper and lower quadrants. Abdominal flat and upright x-rays are taken and reviewed with Dr. Aye. He does not feel that there is a bowel obstruction, but does feel that he has a large amount of stool, and that is probably what is causing him some discomfort. He does have a fluid level that is present.

A: Constipation.

P: He is given a bottle of mag citrate today to drink, and he was encouraged to drink plenty of fluids over the next 24 hours. Eat a very light lunch and supper. I will follow up with him tomorrow morning. If he is not having any significant improvement at that time, we will probably need to give him enemas.

Imo Powell, RN, CNP/mt196
D: 07/26/06 T: 07/26/06 JOB#: 8935
Dictated, but not reviewed

Medical Consult MCF-SCL **MICHAELSON, Barry** **OID#: 203279** **July 27, 2006**

S: The patient comes in today for followup of a visit yesterday. Please see previous dictation. Yesterday, he was given a bottle of mag citrate to drink and an order for Tylenol. He said that he had one larger stool and some diarrhea from the mag citrate but still feels as if he has a lot of gas and bloating. He denies having any heartburn. He continues to have no appetite and a little bit of nausea, but he has not had any vomiting. He did drink fluids yesterday, and he has been able to keep that down. He actually felt a little bit better yesterday for a while, and then during the night, he had pain and described it almost like a grabbing-type sensation and cramping in the abdomen.

O: The abdomen is round and slightly distended.

A: Constipation.

P: He is given another bottle of mag citrate today, as well as a Fleets enema. I have scheduled him back to see Dr. Krueger tomorrow in my absence.

Imo Powell, RN, CNP/mt196
D: 07/27/06 T: 07/27/06 JOB#: 9102
Dictated, but not reviewed

NAME _____ OID _____

5070020045 **PRACTITIONER NOTES** MINNCOR

STATE OF MINNESOTA
Department of Corrections

DATE & TIME	
6/19/06	Here for PE, Please see form — DPowell RNCNP
6-22-06	Old DOC Chart reviewed — DPowell RNCNP

Medical Consult MCF-SCL **MICHAELSON, Barry Scott OID#: 203279** **July 18, 2006**

S: The patient signed up for sick call today because of a rash on his neck. He actually signed up for sick call yesterday, and was given an order for hydrocortisone cream, but of course, that has not arrived yet. He, subsequently, ended up signing up for sick call again. He states the rash started on the 07/15/06 when it was extremely hot. He said it involves his hair follicles on the legs and arms, a little bit on his chest, but his neck is what was sweating profusely over the weekend, and now it is itching and he has scratched to the point where he is having a lot of discomfort in that area.

O: Blood pressure 123/78, pulse 89, temperature 97. He has a mild folliculitis likely related to the heat on the lower and upper extremities. On the posterior aspect of his neck he has an area that is extremely erythematous and dry. There is no evidence of infection at this time.

A: Dermatitis.

P: I will give the patient hydrocortisone cream 1% apply three times daily. I did give the patient a tube of this from stock today so he would begin using it immediately. We will schedule him back for followup in one week.

Imo Powell, RN, CNP/mt5
D: 07/18/06 T: 07/18/06 JOB#: 7886
Dictated, but not reviewed

Medical Consult MCF-SCL **MICHAELSON, Barry** **OID#: 203279** **July 24, 2006**

S: The patient comes in today for followup of his dermatitis that he had on his neck. He said it is almost getting close to being gone. He said he still has a little bit of itching, but he has not been scratching this area.

O: On the posterior aspect of his neck, the area that was extremely erythematous and dry is much improved. He has a little bit of erythema and some drying that is still present, but no evidence of infection.

A: Dermatitis.

P: Continue with the hydrocortisone cream three times a day for the next 10 days. Follow up as needed for continued problems or recurrent.

Imo Powell, RN, CNP/mt5872
D: 07/24/06 T: 07/24/06 JOB#: 8618
Dictated, but not Reviewed

7-26-06 early mon AM pain mid abd mild pain worse since yesterday appetite ↓ nausea & vomiting Bm's - yesterday 8935 See next page

OID

203279 9/16/1964

MICHAELSON, BARRY SCOTT

PRACTITIONER NOTES

13-58B

Services Progress Notes

203279 9/16/1964

MICHAELSON, BARRY

Inmate/Resident #

Allergies:

Date	Time	Notes
11/6/07	1:38PM	(S) F/U facial trauma.
		(O) cut wound below Rt eye is healing nicely c̄ no complications. Also, Rt eye sub conjunctiva Hge is subsiding O.K.
		(A) cut wound of the face - Rt eye sub conj. Hge Healing nicely
		(P) RTC prn
		98° 136/92 [signature]

Property of Corrections Corporation of America MAR 2006

BioReference LABORATORIES

FINAL REPORT

DOCTOR
SHAMAN, EDWARD
MN316 - MCF - FARIBAULT
1101 LINDEN LANE,
FARIBAULT, MN 55021
Acct #: (MN316) MO
P: (507)334-0734

PATIENT
LIGONS, RONALDO SYLVESTER
DOB: 09/29/1953 Age: 61 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address: ,
,
P:

SAMPLE
Specimen ID: 108538929
Date Of Report: 06/25/2015 03:58
Date Collected: 06/24/2015 10:42
Date Received: 06/24/2015 22:10
North America Central Time

Notes: PATIENT FASTING

CLINICAL REPORT

-* CARDIOVASCULAR/LIPIDS *--

Test	Result	Abnormal	Reference	Units	Previous Result	Date
Cholesterol	132		<200	mg/dL	151	04/28/2014
Triglycerides	128		<150	mg/dL	139	04/28/2014
HDL CHOL., DIRECT	54		>40	mg/dL	59	04/28/2014
HDL as % of Cholesterol	41		>14	%	39	04/28/2014
Evaluation: BELOW AVERAGE RISK						
Chol/HDL Ratio	2.4		<7.4		2.6	04/28/2014
Evaluation: BELOW AVERAGE RISK						
LDL/HDL Ratio	0.96		<3.56		1.08	04/28/2014
NON-HDL CHOLESTEROL	78		<130	mg/dL		
LDL Cholesterol	52		<100	mg/dL	64	04/28/2014
VLDL, CALCULATED	26		7-32	mg/dL	28	04/28/2014

NOTE: Patients taking N-acetylcysteine (NAC, an OTC mucolytic agent) or acetaminophen in large doses (leading to elevated levels of the metabolite NAPQI) may have falsely low levels of the following analytes in blood or urine due to drug interference: Cholesterol, HDL, LDL, Triglycerides, Uric Acid (serum and urine). (Roche Diagnostics Communication, 5/7/15)

6/26/15 11:20

EXHIBIT B 4 03-11-16 CW

PENGAD 800-631-6989

BioReference LABORATORIES

FINAL REPORT

DOCTOR
NELSON, JERRY ALAN
MN316 - MCF- FARIBAULT
1101 LINDEN LANE,
FARIBAULT, MN 55021
Acct #: (MN316) MO
P: (507)334-0734

[redacted]
LIGONS, RONALDO SYLVESTER
DOB: 09/29/1953 Age: 61 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address:,
,
P:

REPORT
Specimen ID: 108278086
Date Of Report: 06/11/2015 05:46
Date Collected: 06/10/2015 11:43
Date Received: 06/10/2015 22:36
North America Central Time

Notes: PATIENT FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

Hemoglobin A1C	7.7 HI

----- MISCELLANEOUS -----

Hemoglobin A1C	7.7 HI	<5.7	%	6.9 HI	03/13/2015

HEMOGLOBIN A1c AND eAG REFERENCE RANGES

A1c(%)	DIABETES CATEGORY*
<5.7	Normal (non-diabetic)
5.7-6.4	Increased risk of diabetes
=>6.5	Consistent with diabetes

A1c(%)	eAG(ESTIMATED AVERAGE PLASMA GLUCOSE)(mg/dL)
6	126
7	154
8	183
9	212
10	240
11	269
12	298

*recommended ranges-American Diabetes Association(2010)

NOTE: Hemolysis, rare hemoglobin variants and thalassemia major may affect glycemic results.

5-21 171203

Laboratory Report Form

____ MCF-St. Cloud 2305 Minnesota Blvd. SE St. Cloud, MN 56302-1000	____ MCF-Moose Lake 1000 Lake Shore Drive Moose Lake, MN 55767-9449	____ MCF-Oak Park Heights 5329 Osgood Ave North Stillwater, MN 55082-0010	____ MCF-Stillwater 970 Picket St. N Bayport, MN 55003-1490	____ MCF-Lino Lakes 7525 4th Ave Lino Lakes, MN 55014-1099
X MCF-Faribault 1101 Linden Lane Faribault, MN 55021-6400	____ MCF-Shakopee 1010 W. 6th Ave Shakopee, MN 55379	____ MCF-Rush City 7600 525th Street Rush City, MN 55069	____ MCF-WR/CIP 86032 Co. Hwy. 61 Willow River, MN 55795	____ MCF-Red Wing 1079 Highway 292 Red Wing, MN 55066

Collection Date & Time 5-26-15 Am

Urinalysis	Miscellaneous Tests	Normals
Color ____	**Blood Sugar:** ____ mg/dl	70 - 110 mg/dl
Character ____	Fasting ____ Yes ____ No	
Glucose ____	**Hemoglobin:** ____ g/dl	Females 12.0 - 15.5 g/dl Males 14.0 - 17.5 g/dl
Bilirubin ____	**Microalbumin:**	
Ketones ____	Albumin ____ mg/L	
Sp. Gr. ____	Creatinine ____ mg/dl	< 30 mg/L
Blood ____	A : C ____ mg/g	10 - 300 mg/dl
pH ____	Protein Screen ____	< 30 mg/g
Protein ____		
Urobilinogen ____		
Nitrates ____		
Leukocytes ____	X **Occult Blood** — **Results**	
Microscopic	Date 5-21-15 — neg	
WBC / HPF ____	Date 5-22-15 — neg	
RBC / HPF ____	Date 5-24-15 — neg	
Bacteria / HPF ____	**Urine HCG** ____	
Epith / HPF ____	**HIV Rapid Test Results:**	
Casts / LPF ____	____ Positive ____ Negative	
Crystals / HPF ____	**Wet Prep**	
Mucous / LPF ____	Bacteria Rare 1+ 2+ 3+	
Misc: ____	WBCs 0 Rare 1+ 2+ 3+	
____ ____	Clue Cells Present Absent	
____ ____	Yeast Present Absent	
	Trichomonas Present Absent	

Signature: Kristen Bass

Date and Time: 5-26-15 8Am

Name LIGons. Ronald OID# 171203 DOB ____ MD GK

5-28-15

[redacted]

BioReference LABORATORIES

FINAL REPORT

ORDER
KILBER, EUGENE
MN316 - MCF- FARIBAULT
1101 LINDEN LANE,
FARIBAULT, MN 55021
Acct #: (MN316) MO
P: 507-334-0832

PATIENT
LIGONS, RONALDO SYLVESTER
DOB: 09/29/1953 Age: 61 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address:,
,
P:

SPECIMEN
Specimen ID: 107055588
Date Of Report: 04/08/2015 07:00
Date Collected: 04/06/2015 07:35
Date Received: 04/06/2015 23:39

Notes: NON FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

HEP C,RNA,IU 5336597 HI HEP C,RNA,(log-10) 6.73 HI

----- MISCELLANEOUS -----

HEP C,RNA,IU	5336597 HI	<15	IU/mL		

HEP C ULTRAQUANT,RNA TEST CODES 8784/8793 INTERPRETATION

HEP C (IU/mL)	Interpretation
<15 ND	Not Detected
<15 D	Detected
15 - >50,000,000	Detected

The COBAS AmpliPrep/COBAS TaqMan HCV Test is not intended for use as the sole diagnostic test to confirm the presence of HCV infection.
NOTE: Results for Roche COBAS AmpliPrep/TaqMan HEP C Ultrasensitive assay reports with a range of <15-50 million IU/mL.

HEP C,RNA,(log-10)	6.73 HI	<1.18	log-10		

4-16-15

BioReference LABORATORIES

FINAL REPORT

DOCTOR: KILBER, EUGENE
MN316 - MCF- FARIBAULT
1101 LINDEN LANE,
FARIBAULT, MN 55021
Acct #: (MN316) MO
P: 507-334-0832

LIGONS, RONALDO SYLVESTER
DOB: 09/29/1953 Age: 61 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address: ,
P:

Specimen ID: 107056056
Date Of Report: 04/08/2015 16:42
Date Collected: 04/06/2015 07:36
Date Received: 04/06/2015 23:52

CLINICAL REPORT

RDW	13.5		10.9-16.9	%	15.6	11/12/2014
POLYS		30.0 LO	36.0-78.0	%	32.7 LO	11/12/2014
POLYS, ABS. COUNT		0.92 LO	1.22-9.20	x10(3)/uL	1.83	11/12/2014
LYMPHS	41.5		12.0-48.0	%	45.3	11/12/2014
LYMPHS, ABS. COUNT	1.27		0.41-5.66	x10(3)/uL	2.53	11/12/2014
MONOS		20.3 HI	0.0-13.0	%	15.7 HI	11/12/2014
MONOS, ABS. COUNT	0.62		0.17-1.42	x10(3)/uL	0.88	11/12/2014
EOS	6.9		0.0-8.0	%	5.0	11/12/2014
EOS, ABS. COUNT	0.21		0.03-0.94	x10(3)/uL	0.28	11/12/2014
BASOS	1.0		0.0-2.0	%	0.9	11/12/2014
BASOS, ABS. COUNT	0.03		0.00-0.24	x10(3)/uL	0.05	11/12/2014
IMMATURE GRANULOCYTES	0.3		0.0-1.6	%	0.4	11/12/2014
Platelet Count	273		144-400	x10(3)/uL	325	11/12/2014
MPV		12.4 HI	8.2-11.9	fL	11.3	11/12/2014

MACROCYTOSIS 1+; ANISOCYTOSIS 1+

NOTE: The CBC results have been confirmed by repeat analysis.

NOTE: One or more parameters of the CBC reported for this accession require a MANUAL peripheral smear differential review and/or cell count. This has been performed as per our protocol and commented on the report, if necessary. This review also included RBC morphology and platelet estimation.

----- MISCELLANEOUS -----

HEPATITIS C GENOTYPE	Type 1b	See Below		

NOTE: Hepatitis C genotype was evaluated and its performance characteristics determined by BioReference Laboratories. It has not been cleared or approved by the FDA, but such clearance or approval is not necessary. It should not be regarded as investigational or for research. The laboratory is certified under the Clinical Laboratory Improvement Act of 1988 (CLIA) as qualified to perform high-complexity clinical testing.

NOTE: Hepatitis C Virus Genotype/Subtype assay is able to identify the following subtypes:
1a, 1b, 1a/1b, 1, 2a/2c, 2b, 2, 3a, 3b, 3c, 3, 3k, 4a/4c/4d, 4b, 4e, 4f, 4h, 4, 5a, 6a/6b, 6 (subtypes c-l)

ASSAY INFORMATION: Test# 2161 (Hepatitis C Genotype) performed using Siemens Versant LIPA Assay.

HIV Ag/Ab	Non-Reactive	Non-Reactive		

Assay Information: Assay for the Detection of Antibodies to Human Immunodeficiency Virus Type 1

4-10-15

BioReference LABORATORIES

FINAL REPORT

KILBER, EUGENE MN316 - MCF- FARIBAULT 1101 LINDEN LANE, FARIBAULT, MN 55021 Acct #: (MN316) MO P: 507-334-0832	LIGONS, RONALDO SYLVESTER DOB: 09/29/1953 Age: 61 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address: , , P:	Specimen ID: 107056056 Date Of Report: 04/08/2015 16:42 Date Collected: 04/06/2015 07:36 Date Received: 04/06/2015 23:52

CLINICAL REPORT

(HIV-1/0) and/or Type 2 (HIV-2) and p24 Antigen. Method: EIA 4th Gen (Bio-Rad Laboratories)

AFP, TUMOR MARKER	18.3 HI	<8.4	ng/mL	11.8 HI	06/01/2012

NOTE: The Roche Alphafetoprotein, TUMOR MARKER assay (test# 0025) is an electrochemiluminescence assay used to aid in the management of patients with germ cell tumors when measured in serial fashion. Results cannot be interpreted as absolute evidence of the presence or absence of malignant disease. Values obtained with different assay methods or kits cannot be used interchangeably.
This test is not interpretable in pregnant females. For AFP, gestational, use test #0825 (AFP3) or test #3158 (AFP4) or test #6323 (AFP5).
ASSAY INFORMATION: Method Electrochemiluminescence Immunoassay (Roche Diagnostics).

BioReference LABORATORIES

FINAL REPORT

DOCTOR: KILBER, EUGENE
MN316 - MCF- FARIBAULT
1101 LINDEN LANE,
FARIBAULT, MN 55021
Acct #: (MN316) MO
P: 507-334-0832

[redacted]: LIGONS, RONALDO SYLVESTER
DOB: 09/29/1953 Age: 61 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address: ,
,
P:

SAMPLE: Specimen ID: 107056056
Date Of Report: 04/08/2015 16:42
Date Collected: 04/06/2015 07:36
Date Received: 04/06/2015 23:52

Notes: NON FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

Glucose	125 HI	AST	49 HI	ALT	48 HI
WBC	3.06 LO	POLYS	30.0 LO	POLYS, ABS. COUNT	0.92 LO
MONOS	20.3 HI	MPV	12.4 HI		
AFP, TUMOR MARKER	18.3 HI				

------* CHEMISTRY *--------					
Total Protein	6.9	5.9-8.4	g/dL	6.8	11/12/2014
Albumin	4.3	3.5-5.2	g/dL	4.4	11/12/2014
Globulin	2.6	1.7-3.7	g/dL	2.4	11/12/2014
A/G Ratio	1.7	1.1-2.9		1.8	11/12/2014
Glucose	125 HI	70-99	mg/dL	95	03/13/2015
Sodium	139	133-145	mmol/L	139	03/13/2015
Potassium	5.0	3.3-5.3	mmol/L	4.1	03/13/2015
Chloride	98	96-108	mmol/L	101	03/13/2015
CO2	25	22-29	mmol/L	27	03/13/2015
BUN	12	8-23	mg/dL	14	03/13/2015
Creatinine	0.88	0.80-1.30	mg/dL	0.71 LO	03/13/2015
e-GFR	88	>60	mL/min	113	03/13/2015
e-GFR, African American	106	>60	mL/min	137	03/13/2015
BUN/Creat Ratio	13.6	10.0-28.0		19.7	03/13/2015
Calcium	10.0	8.6-10.4	mg/dL	9.1	03/13/2015
Bilirubin, Total	0.4	<1.2	mg/dL	0.5	11/12/2014
NOTE: New reference range for Bilirubin, Total effective 2-11-2015.					
Alk Phos	130	40-156	U/L	124	11/12/2014
AST	49 HI	<40	U/L	36	11/12/2014
ALT	48 HI	<41	U/L	44 HI	11/12/2014
------* HEMATOLOGY *--------					
WBC	3.06 LO	3.40-11.80	x10(3)/uL	5.59	11/12/2014
RBC	5.13	4.20-5.90	x10(6)/uL	4.98	11/12/2014
HGB	13.8	12.3-17.0	gm/dL	13.9	11/12/2014
HCT	41.8	39.3-52.5	%	40.7	11/12/2014
MCV	81.5	80.0-100.0	fL	81.7	11/12/2014
MCH	26.9	25.0-34.1	pg	27.9	11/12/2014
MCHC	33.0	29.0-35.0	gm/dL	34.2	11/12/2014

BioReference LABORATORIES

FINAL REPORT

DOCTOR	PATIENT	SAMPLE
DANNEWITZ, STEPHEN MN316 - MCF- FARIBAULT 1101 LINDEN LANE, FARIBAULT, MN 55021 Acct #: (MN316) MO P: 507-334-0832	LIGONS, RONALDO SYLVESTER DOB: 09/29/1953 Age: 61 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address: , , P:	Specimen ID: 106633021 Date Of Report: 03/14/2015 05:55 Date Collected: 03/13/2015 06:15 Date Received: 03/13/2015 23:52

Notes: PATIENT FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

Creatinine	0.71 LO
Hemoglobin A1C	6.9 HI

-------* CHEMISTRY *--------						
Test	Result	Abnormal	Reference	Units	Previous Result	Date
Glucose	95		70-99	mg/dL	87	02/24/2015
Sodium	139		133-145	mmol/L	140	02/24/2015
Potassium	4.1		3.3-5.3	mmol/L	4.6	02/24/2015
Chloride	101		96-108	mmol/L	99	02/24/2015
CO2	27		22-29	mmol/L	29	02/24/2015
BUN	14		8-23	mg/dL	15	02/24/2015
Creatinine		0.71 LO	0.80-1.30	mg/dL	0.80	02/24/2015
e-GFR	113		>60	mL/min	98	02/24/2015
e-GFR, African American	137		>60	mL/min	119	02/24/2015
BUN/Creat Ratio	19.7		10.0-28.0		18.8	02/24/2015
Calcium	9.1		8.6-10.4	mg/dL	9.5	02/24/2015
-----* MISCELLANEOUS *------						
Hemoglobin A1C		6.9 HI	<5.7	%	7.1 HI	02/24/2015

HEMOGLOBIN A1c AND eAG REFERENCE RANGES

A1c(%)	DIABETES CATEGORY*
<5.7	Normal (non-diabetic)
5.7-6.4	Increased risk of diabetes
=>6.5	Consistent with diabetes

A1c(%)	eAG(ESTIMATED AVERAGE PLASMA GLUCOSE)(mg/dL)
6	126
7	154
8	183
9	212
10	240
11	269
12	298

*recommended ranges-American Diabetes Association(2010)

NOTE: Hemolysis, rare hemoglobin variants and thalassemia major may affect glycemic results.

SRD 3-16-15

BioReference LABORATORIES

FINAL REPORT

DOCTOR	PATIENT	SAMPLE
DANNEWITZ, STEPHEN MN316 - MCF- FARIBAULT 1101 LINDEN LANE, FARIBAULT, MN 55021 Acct #: (MN316) MO P: 507-334-0832	LIGONS, RONALDO SYLVESTER DOB: 09/29/1953 Age: 61 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address: , , P:	Specimen ID: 106635906 Date Of Report: 03/15/2015 01:44 Date Collected: 03/13/2015 06:16 Date Received: 03/13/2015 23:12

Notes: PATIENT FASTING

CLINICAL REPORT

-----* MISCELLANEOUS *------						
Test	Result	Abnormal	Reference	Units	Previous Result	Date
CREAT.URN.TIMED/RAND	91.4		Not Estab.	mg/dL	*37.1*	02/24/2015
MICROALB/CREAT RATIO	16.4		<30.0	mg/g creat	*Can't Calc*	02/24/2015
MICROALBUMIN,RANDOM	1.5		Not Estab.	mg/dL	*<1.2*	02/24/2015

SP 3-16-15

BioReference LABORATORIES

FINAL REPORT

DOCTOR	PATIENT	SAMPLE
PROSSER, RACHEL	LIGONS, RONALDO SYLVESTER	Specimen ID: 106307888
MN316 - MCF- FARIBAULT	DOB: 09/29/1953 Age: 61 Y Sex: M	Date Of Report: 02/25/2015 08:26
1101 LINDEN LANE,	U/FL: Bed:	Date Collected: 02/24/2015 06:15
FARIBAULT, MN 55021	Rm:	Date Received: 02/24/2015 23:54
Acct #: (MN316) MD	Patient ID: 171203	
P: 507-334-0832	Address: ,	
	,	
	P:	

Notes: PATIENT FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

Hemoglobin A1C	7.1 HI

Test	Result	Abnormal	Reference	Units	Previous Result	Date
-------* CHEMISTRY *--------						
Glucose	87		70-99	mg/dL	132 HI	11/12/2014
Sodium	140		133-145	mmol/L	140	11/12/2014
Potassium	4.6		3.3-5.3	mmol/L	4.7	11/12/2014
Chloride	99		96-108	mmol/L	96	11/12/2014
CO2	29		22-29	mmol/L	26	11/12/2014
BUN	15		8-23	mg/dL	16	11/12/2014
Creatinine	0.80		0.80-1.30	mg/dL	0.90	11/12/2014
e-GFR	98		>60	mL/min	107	11/12/2014
e-GFR, African American	119		>60	mL/min	129	11/12/2014
BUN/Creat Ratio	18.8		10.0-28.0		17.8	11/12/2014
Calcium	9.5		8.6-10.4	mg/dL	10.0	11/12/2014
-----* MISCELLANEOUS *------						
Hemoglobin A1C	7.1 HI		<5.7	%	7.1 HI	11/12/2014

GLYCOHEMOGLOBIN A1C AND eAG REFERENCE RANGES

A1C(%)	DIABETES CATEGORY*
<5.7	Normal (non-diabetic)
5.7-6.4	Increased risk of diabetes
=>6.5	Consistent with diabetes

A1C(%)	eAG(ESTIMATED AVERAGE PLASMA GLUCOSE)(mg/dL)
6	126
7	154
8	183
9	212
10	240
11	269
12	298

*recommended ranges-American Diabetes Association(2010)

NOTE: Hemolysis, rare hemoglobin variants and thalassemia major may affect glycemic results.

CREAT.URN.TIMED/RAND	37.1	Not Estab.	mg/dL	20.6	05/05/2014
MICROALB/CREAT RATIO	Can't Calc	<30.0	mg/g creat	281.6 HI	05/05/2014
MICROALBUMIN,RANDOM	<1.2	Not Estab.	mg/dL	5.8	05/05/2014

NOTE: We are unable to calculate the microalbumin/creatinine ratio when the microalbumin result is less than 1.2 mg/dL. A result of

2-25-15

BioReference LABORATORIES

FINAL REPORT

DOCTOR	PATIENT	SAMPLE
PROSSER, RACHEL	LIGONS, RONALDO SYLVESTER	Specimen ID: 106307888
MN316 - MCF- FARIBAULT	DOB: 09/29/1953 Age: 61 Y Sex: M	Date Of Report: 02/25/2015 08:26
1101 LINDEN LANE,	U/FL: Bed:	Date Collected: 02/24/2015 06:15
FARIBAULT, MN 55021	Rm:	Date Received: 02/24/2015 23:54
Acct #: (MN316) MO	Patient ID: 171203	
P: 507-334-0832	Address: ,	
	,	
	P:	

CLINICAL REPORT

Test	Result	Abnormal	Reference	Units	Previous Result	Date

<1.2 mg/dL would result in a ratio in the normal range.

Can't Calc: One or more components was outside the measurable range. We are unable to calculate.

BioReference LABORATORIES

FINAL REPORT

QUIRAM, DARRYL MN322 - MCF - STILLWATER 970 PICKETT ST., BAYPORT, MN 55003 Acct #: (MN322) FX P: 651-779-2700	LIGONS, RONALDO DOB: 09/29/1953 Age: 61 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address:, , P:	Specimen ID: 105456449 Date Of Report: 01/08/2015 13:38 Date Collected: 01/06/2015 13:50 Date Received: 01/06/2015 23:02

CLINICAL REPORT

MICROBIOLOGY

CULTURE, THROAT	NORMAL RESPIRATOR ...	NORMAL FLORA		

NORMAL RESPIRATORY FLORA. NO BETA HEMOLYTIC STREPTOCOCCI GROUPS A, C OR G ISOLATED.
SOURCE: THROAT

1/7/2015.

BioReference LABORATORIES

FINAL REPORT

DOCTOR
QUIRAM, DARRYL
MN322 - MCF - STILLWATER
970 PICKETT ST.,
DAYPORT, MN 55003
Acct #: (MN322) FX
P: 651-779-2700

PATIENT
LIGONS, RONALDO
DOB: 09/29/1993 Age: 21 Y Sex: M
U/FL: Bed:
Rm:
Patient ID: 171203
Address: ,
, MN
P:

SAMPLE
Specimen ID: 104606486
Date Of Report: 11/13/2014 07:27
Date Collected: 11/12/2014 08:00
Date Received: 11/12/2014 23:12

Notes: PATIENT FASTING

CLINICAL REPORT

Clinical Abnormalities Summary: (May not contain all abnormal results; narrative results may not have abnormal flags. Please review entire report.)

Glucose	132 HI	ALT	44 HI
POLYS	32.7 LO	MONOS	15.7 HI
Hemoglobin A1C	7.1 HI		

Test	Result	Abnormal	Reference	Units	Previous Result (Date)	
-------* CHEMISTRY *--------						
Total Protein	6.8		5.9-8.4	g/dL	6.9	07/23/2014
Albumin	4.4		3.5-5.2	g/dL	4.5	07/23/2014
Globulin	2.4		1.7-3.7	g/dL	2.4	07/23/2014
A/G Ratio	1.8		1.1-2.9		1.9	07/23/2014
Glucose		132 HI	70-99	mg/dL	121 HI	07/23/2014
Sodium	140		133-145	mmol/L	134	07/23/2014
Potassium	4.7		3.3-5.3	mmol/L	5.0	07/23/2014
Chloride	96		96-108	mmol/L	95 LO	07/23/2014
CO2	26		22-29	mmol/L	26	07/23/2014
BUN	16		6-20	mg/dL	12	07/23/2014
Creatinine	0.90		0.90-1.30	mg/dL	0.73 LO	07/23/2014
e-GFR	107		>60	mL/min	137	07/23/2014
e-GFR, African American	129		>60	mL/min	166	07/23/2014
BUN/Creat Ratio	17.8		10.0-28.0		16.4	07/23/2014
Calcium	10.0		8.6-10.4	mg/dL	10.2	07/23/2014
Bilirubin, Total	0.5		0.2-1.0	mg/dL	0.4	07/23/2014
Alk Phos	124		40-156	U/L	120	07/23/2014
AST	36		<40	U/L	43 HI	07/23/2014
ALT		44 HI	<41	U/L	45 HI	07/23/2014
------* HEMATOLOGY *--------						
WBC	5.59		3.40-11.80	x10(3)/uL	5.86	07/23/2014
RBC	4.98		4.20-5.90	x10(6)/uL	4.89	07/23/2014
HGB	13.9		12.3-17.0	gm/dL	13.0	07/23/2014
HCT	40.7		39.3-52.5	%	40.0	07/23/2014
MCV	81.7		80.0-100.0	fL	81.8	07/23/2014
MCH	27.9		25.0-34.1	pg	26.6	07/23/2014
MCHC	34.2		29.0-35.0	gm/dL	32.5	07/23/2014
RDW	15.6		10.9-16.9	%	15.9	07/23/2014
POLYS		32.7 LO	36.0-78.0	%	33.5 LO	07/23/2014
POLYS, ABS. COUNT	1.83		1.22-9.20	x10(3)/uL	1.96	07/23/2014

BioReference LABORATORIES

FINAL REPORT

QUIRAM, DARRYL MN322 - MCF - STILLWATER 970 PICKETT ST., BAYPORT, MN 55003 Acct #: (MN322) FX P: 651-779-2700	LIGONS, RONALDO DOB: 09/29/1993 Age: 21 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address: , , MN P:	Specimen ID: 184606486 Date Of Report: 11/13/2014 07:27 Date Collected: 11/12/2014 08:00 Date Received: 11/12/2014 23:12

CLINICAL REPORT

LYMPHS	45.3		12.0-48.0	%	46.6	07/23/2014
LYMPHS, ABS. COUNT	2.53		0.41-5.66	x10(3)/uL	2.73	07/23/2014
MONOS		15.7 HI	0.0-13.0	%	13.1 HI	07/23/2014
MONOS, ABS. COUNT	0.88		0.17-1.42	x10(3)/uL	0.77	07/23/2014
EOS	5.0		0.0-8.0	%	6.1	07/23/2014
EOS, ABS. COUNT	0.28		0.03-0.94	x10(3)/uL	0.36	07/23/2014
BASOS	0.9		0.0-2.0	%	0.5	07/23/2014
BASOS, ABS. COUNT	0.05		0.00-0.24	x10(3)/uL	0.03	07/23/2014
IMMATURE GRANULOCYTES	0.4		0.0-1.6	%	0.2	07/23/2014
Platelet Count	325		140-400	x10(3)/uL	[illegible]	07/23/2014
MPV	11.3		8.2-11.9	fL	10.7	07/23/2014
------ MISCELLANEOUS ------						
Hemoglobin A1C		7.1 HI	<5.7	%	7.3 HI	06/11/2014

GLYCOHEMOGLOBIN A1C AND eAG REFERENCE RANGES

A1C(%)	DIABETES CATEGORY*
<5.7	Normal (non-diabetic)
5.7-6.4	Increased risk of diabetes
=>6.5	Consistent with diabetes

A1C(%)	eAG(ESTIMATED AVERAGE PLASMA GLUCOSE)(mg/dL)
6	126
7	154
8	183
9	212
10	240
11	269
12	298

*recommended ranges-American Diabetes Association(2010)

NOTE: Rare hemoglobin variants and thalassemia major may affect glycemic results.

BioReference LABORATORIES

FINAL REPORT

DOCTOR	PATIENT	SAMPLE
QUIRAM, DARRYL MN322 - MCT - STILLWATER 970 PICKETT ST., BAYPORT, MN 55003 Acct #: (MN322) FX P: 651-779-2700	LIGONS, RONALDO DOB: 09/29/1993 Age: 20 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address:, , MN P:	Specimen ID: 183104762 Date Of Report: 08/22/2014 10:33 Date Collected: 08/20/2014 09:00 Date Received: 08/20/2014 23:14

Notes: NON FASTING

CLINICAL REPORT

Test	Result	Abnormal	Reference	Units	Previous Result	Date
------* URINALYSIS *--------						
Color	YELLOW		YELLOW, STRAW, AMBER		YELLOW	12/17/2013
Character	CLEAR		CLEAR		CLEAR	12/17/2013
Specific Gravity URN	1.009		1.003 - 1.030		1.013	12/17/2013
pH Urine	6.0		5.0 - 8.0		6.5	12/17/2013
Protein, Urine	NEGATIVE		NEGATIVE		1+, 30 mg/dL *	12/17/2013
Glucose, Urine	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Ketone, Urine	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Urobilinogen Urine	0.2		0.2 - 1.0	Units	1.0	12/17/2013
Bilirubin, Urine	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Blood, Urine	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Nitrites Urine	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Leukocyte Esterase	NEGATIVE		NEGATIVE		NEGATIVE	12/17/2013
Crystals Urine	NONE		NONE		NONE	12/17/2013
Crystal Amt. Urine	NONE		NONE		NONE	12/17/2013
WBC, Urine	0-4		0-4	PER HPF	0-4	12/17/2013
RBC, Urine	NONE SEEN		NONE SEEN	PER HPF	NONE SEEN	12/17/2013
Epithelial Cells, Ur	NONE		FEW		NONE	12/17/2013
Cast, Hyaline, Urine	0-4		0-4	PER LPF	0-4	12/17/2013
Cast, Granular, Urin	NONE SEEN		0-1	PER LPF	NONE SEEN	12/17/2013
Cast, RBC, Urine	NONE SEEN		0-1	PER LPF	NONE SEEN	12/17/2013
Bacteria, Urine	NONE		FEW		NONE	12/17/2013
------* MICROBIOLOGY *--------						
CULTURE, URINE	NO GROWTH		NO GROWTH			
SOURCE: URINE						
-----* MISCELLANEOUS *------						
C.TRACH.,AMPLI.	Negative		Negative			
N.GONOR.AMP.DNA	Negative		Negative			

NOTE: Test# 3800 and 2661 (GC and Chlamydia, Amplified DNA) performed using BD Probetec Amplified DNA Assay.
NOTE: Rare cross-reactivity may occur in the BD Probetec amplified DNA GC assay due to certain strains of N.cinerea, N.subflava and N.lactamica.

25 Aug 2014

BioReference LABORATORIES

FINAL REPORT

QUIRAM, DARRYL MN322 - MCF - STILLWATER 970 PICKETT ST., DAYPORT, MN 55003 Acct #: (MN322) FX P: 651-779-2700	LIGONS, RONALDO DOB: 09/29/1993 Age: 20 Y Sex: M U/FL: Bed: Rm: Patient ID: 171203 Address:, , MN P:	Specimen ID: 102855306 Date Of Report: 08/12/2014 14:15 Date Collected: 08/05/2014 10:00 Date Received: 08/06/2014 23:46

Notes: NON FASTING

CLINICAL REPORT

MISCELLANEOUS

Pregabalin (Lyrica) (7)	3.3	0.10	mcg/mL		

Synonym(s): Lyrica(R)
Therapeutic drug concentrations have not been established for any indication at this time.
Mean peak plasma concentrations up to 9.5 mcg/mL have been reported approximately 1 hour post-administration of up to 300 mg orally.
Analysis by High Performance Liquid Chromatography/Tandem Mass Spectrometry (LC-MS/MS) (7)
Performed by: National Medical Lab
2300 Stratford Ave.
Willow Grove, PA 19090

2/13/14

Minnesota Department of Corrections
Minnesota Correctional Facility - Faribault
Grievance Report - 5093

OID 171203 **Living Assignment** MCF-FRB K2 D Tier 1 123 02 Lower Bunk
Name Ligons, Ronaldo Sylvester **Case Worker** Haffely, Jeffrey J

Grievance Facility: Faribault
Group: Medical
Type: Prescriptions, Medication

Grievance:

This is a rewrite of my 4-10-15 Grievance attached. The issue is specified out in this packet dated 4-10-15 and is now exhausted prior to this 5-5-15 grievance. It involves the year-long denial of a 12 week, 1 pill per day cure for HCV infection via Soudall or Simicar product.

Institution File Date: 05/08/2015

Institution Response:

Your records have been reviewed by medical providers based on the revised DOC criteria for hepatitis C treatment. You have refused a CD evaluation in 2015. In the absence of evidence of cirrhosis or advanced fibrosis (stage 3), DOC guidelines require completion of CD treatment if directed to this by the Department. You had a liver biopsy in 2005 that showed stage 2 fibrosis. Your current FIB4 score for evidence of advanced fibrosis is 1.58 (the low range of intermediate risk). This is indicative of low risk of advanced fibrosis and not consistent with significant progression of fibrosis since your last liver biopsy. At this level of FIB4 score, the CD treatment criterion applies.

The highest priority for treatment as recommended by AASLD includes stages 3 and 4 fibrosis (FIB4 score greater than 3.25). The CD requirement is waived at this level. The next priority, high priority, includes stage 2 and diabetes with insulin resistance. Your Hgb A1C is 7.1 which is not indicative of insulin resistance.

At this time, you do not meet the revised DOC criteria for hepatitis C treatment or repeat liver biopsy.

Institution Response Type: Dismiss
Institution Response Person: Karow, Nola R.
Institution Response Date: 05/26/2015

EXHIBIT #5 (3-11-16) CW
PENGAD 800-631-6989

Minnesota Department of Corrections
Minnesota Correctional Facility - Faribault
Grievance Report - 5093

OID 171203 **Living Assignment** MCF-FRB K2 D Tier 1 123 02 Lower Bunk
Name Ligons, Ronaldo Sylvester **Case Worker** Haffely, Jeffrey J

Appeal:

Appellant has attached a detailed document for this appeal. The basic reasons are -

1. CD treatment is not federally required and is an impediment to medical cure.

2. There is no court order for CD treatment.

3. HCU treatment is given without CD treatment.

4. Denials violate Constitutional rights of equal protection, 8th and 14th Amendments to State and Federal Constitutions. And is deliberately indifferent to serious medical needs.

5. Affiant has insulin resistance and uses insulin and oral medication for diabetes to overcome insulin resistance.

Appeal must be granted.

Appeal File Date: 06/16/2015
Appeal Response:
Appeal Response Type:
Appeal Response Person:
Appeal Response Date:

Signature Date

Minnesota Department of Corrections
Grievance Appeal

16F4+5?

Date: 5-27-15

~~Offender~~: RONALD LIGONS OID: 176203 Living Unit: K2D-(2-123)

Instruction to offender: The grievance must be attached to this form in order to process. You may add one 8 1/2 x 11 inch sheet of paper to expand upon your grievance appeal information. Please include one copy of all exhibits for this grievance appeal.

Reason for Appeal: APPELLANT HAS ATTACHED A DETAILED DOCUMENT FOR THIS APPEAL - THE BASIC REASONS ARE:

1- CD TREATMENT IS NOT FEDERALLY REQUIRED AND IS AN IMPEDIMENT TO MEDICAL CURE.

2- THERE IS NO COURT ORDER FOR CD TREATMENT.

3- HCV TREATMENT IS GIVEN WITHOUT CD TREATMENT.

4. DENIALS VIOLATE CONSTITUTIONAL RIGHTS OF EQUAL PROTECTION, 8th & 14th AMENDMENTS TO STATE, & FEDERAL CONSTITUTIONS, AND IS DELIBERATELY INDIFFERENT TO SERIOUS MEDICAL NEEDS

5. AFFIANT HAS INSULIN RESISTANCE, AND USES INSULIN, AND ORAL MEDICATIONS FOR DIABETES TO OVERCOME INSULIN RESISTANCE.

APPEAL MUST BE GRANTED.

Ronald Ligons

RECEIVED
JUN 12 2015
POLICY & LEGAL SERVICES

Dist.
Original - Central Office Grievance Appeal Coordinator
Copies - Facility Grievance Coordinator
Offender

Date Entered _____
Grievance Number _____

303.100C 9/02

MINNCOR

GRIEVANCE APPEAL

RONALDO S. LIGONS 5/27/15

171203

MCF-FARIBAULT

FARIBAULT, MN 55021

I AM APPEALING THE DENIAL OF MY 5/5/15 GRIEVANCE FOR THE FOLLOWING REASONS.

1. I HAVE NOT REFUSED CD TREATMENT, MY CLEAR STATEMENT ON THE DOCUMENTS THAT I SIGNED WAS: "NOT AT THIS TIME, AWAITING MEDICAL/LEGAL DECISIONS" OR THE SUBSTANCE OF THIS.
2. I AM NOT UNDER ANY COURT ORDER FOR CHEMICAL DEPENDENCY TREATMENT. I HAVE NEVER BEEN CHEMICALLY DEPENDENT.
3. THE FEDERAL BUREAU OF PRISONS HAS ADOPTED THE ONE PILL PER DAY CURE FOR HCV INFECTION, AND IT DOES NOT REQUIRE CD. TREATMENT, OR ALLOW SUCH BARRIERS TO CURE OF THIS LIFE-THREATENING DISEASE.
4. HEALTH AND HUMAN SERVICES, (H.H.S.) OF WHICH THE MN DOC MEDICAL DIRECTOR APPEARS TO ALSO HEAD, DOES NOT REQUIRE CD TREATMENT FOR CO-INFECTED PATIENTS WITH HIV/HCV. THE ORAL CURE IS GIVEN.
5. THE DENIAL OF THE ORAL CURE BASED ON A "STAGE 2 FIBROSIS", AND "F1B4 SCORE...1.58" AND THE REQUIREMENT OF CD TREATMENT IS A VIOLATION OF CONSTITUTIONAL RIGHTS, AND INCLUDES BUT IS NOT LIMITED TO A DENIAL OF EQUAL PROTECTION, AND VIOLATION OF 8th, AND FOURTEENTH AMENDMENTS TO THE U.S., AND STATE CONSTITUTIONS.
6. THE "HIGHEST PRIORITY" WAIVER OF CD TREATMENT FOR ADVANCED FIBROSIS' SCORES IS A VIOLATION OF THE CONSTITUTIONAL PROTECTIONS IN 5., ABOVE, AND IS ALSO "DELIBERATE INFIFFERENCE" TO A SERIOUS MEDICAL NEED. THIS IS SO BECAUSE RESPONDENTS WANT APPELLANT TO WAIT UNTIL HE HAS SUFFERED MORE PAIN, LOSS, AND THREATS TO HIS LIFE BEFORE CURING A DISEASE THAT IS WITHIN THEIR POWER AND AUTHORITY.

7. THE CLAIM THAT APPELLANTS' "DIABETIC A1C 7.1,... IS NOT INDICATIVE OF INSULIN RESISTANCE" IS WITHOUT MERIT AS RESPONDENTS KNOW THAT APPELLANT TAKES THE MAXIMUM DOSE OF 2500 MG OF METFORMIN PILLS DAILY, AND 2 SHOTS OF 35 ML 70/30 INSULIN IN A.M., AND P.M. THE 7.1 A1C IS THE RESULT OF *CONTROLLING* DIABETES, NOT INDICATIVE OF A LACK OF RESISTANCE.

FOR ALL OF THE FORGOING REASONS THIS APPEAL MUST BE GRANTED.

RONALDO S. LIGONS
171203

Minnesota Department of Corrections
Minnesota Correctional Facility - Faribault
Grievance Report - 5093

OID	171203	**Living Assignment**	MCF-FRB K2 D Tier 1 123 02 Lower Bunk
Name	Ligons, Ronaldo Sylvester	**Case Worker**	Haffely, Jeffrey J

Grievance Facility: Faribault

Group: Medical

Type: Prescriptions, Medication

Grievance:

This is a rewrite of my 4-10-15 Grievance attached. The issue is specified out in this packet dated 4-10-15 and is now exhausted prior to this 5-5-15 grievance. It involves the year-long denial of a 12 week, 1 pill per day cure for HCV infection via Soudali or Simicar product.

Institution File Date: 05/08/2015

Institution Response:

Your records have been reviewed by medical providers based on the revised DOC criteria for hepatitis C treatment. You have refused a CD evaluation in 2015. In the absence of evidence of cirrhosis or advanced fibrosis (stage 3), DOC guidelines require completion of CD treatment if directed to this by the Department. You had a liver biopsy in 2005 that showed stage 2 fibrosis. Your current FIB4 score for evidence of advanced fibrosis is 1.58 (the low range of intermediate risk). This is indicative of low risk of advanced fibrosis and not consistent with significant progression of fibrosis since your last liver biopsy. At this level of FIB4 score, the CD treatment criterion applies.

The highest priority for treatment as recommended by AASLD includes stages 3 and 4 fibrosis (FIB4 score greater than 3.25). The CD requirement is waived at this level. The next priority, high priority, includes stage 2 and diabetes with insulin resistance. Your Hgb A1C is 7.1 which is not indicative of insulin resistance.

At this time, you do not meet the revised DOC criteria for hepatitis C treatment or repeat liver biopsy.

Institution Response Type: Dismiss

Institution Response Person: Karow, Nola R.

Institution Response Date: 05/26/2015

Signature

5-26-15
Date

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5/26/2015 11:04:03 AM

COPY 1 OF 5

Minnesota Department of Corrections
Offender Grievance

Date: 5-5-15

~~Offender~~: R. LIGONS OID: 171203 Living Unit/Cell/Room#: _____

Casemanager: HAFFLEY

Instruction to offender – You may add one 8½ X 11 inch sheet of paper to expand your grievance information. You must attach kites, including staff response, showing your attempt to resolve the issue informally and one copy of all supporting exhibits for this grievance. Your grievance will be returned if you do not attach kites.

Grievance: THIS IS A RE-WRITE OF MY 4-10-15 GRIEVANCE ATTACHED (1 OF 3). THE ISSUE IS SPELLED OUT IN THIS PACKET DATED 4-10-15 AND IS NOW EXHAUSTED PRIOR TO THIS 5-5-15 GRIEVANCE. IT INVOLVES THE YEAR + LONG DENIAL OF A 12 WEEK, 1 PILL PER DAY CURE FOR HCV INFECTION VIA SOVALDI, OR SIMILAR PRODUCT.

PLEASE EXPEDITE, RETURN ALL DOCUMENTS PER POLICY.

Dist. Original - Facility Grievance Coordinator
Copy - Offender

Date entered _____
Grievance number _____

303.100B (6/2009)

1 OF 3

Minnesota Department of Corrections
Offender Grievance

Date: 4-10-15

~~Offender:~~ RONALDO LIGONS OID: 171203 Living Unit/Cell/Room#: K3B-114-2

Casemanager: ~~HAFFLEY~~

Instruction to offender – You may add one 8½ X 11 inch sheet of paper to expand your grievance information. You must attach kites, including staff response, showing your attempt to resolve the issue informally and one copy of all supporting exhibits for this grievance. Your grievance will be returned if you do not attach kites.

Grievance:

RE: DENIAL OF TREATMENT FOR HCV-INFECTION WITH 12 WEEK ORAL CURE. A RESPONSE IS LONG PAST DUE FOR ANSWERS TO MY KITES, AND PREVIOUS GRIEVANCE FILED WITH THE DOC. (ATTACHED). THE DOC IS A SINGLE SYSTEM AND MATTERS OF THIS LIFE-THREATENING IMPORTANCE DESERVE RESPONSES IN A TIMELY MANNER. ADDITIONALY, THE "CHAIN OF COMMAND" SHOULD NEVER FUNCTION TO STALL RESULTS.

MY FILES DO NOT REFLECT ANY RESPONSES TO (FRB) FILED KITES OF INQUIRY ABOUT ORAL CURE TREATMENT, OR LOCATION OF 1-13-15 GRIEVANCE.

PLEASE RETURN ALL ORIGINAL DOCUMENTS PER POLICY. CC: FILES

Dist. Original - Facility Grievance Coordinator
Copy - Offender

Date entered _____
Grievance number _____

303.100B (6/2009)

Confidential - Private Government Data

1 OF 2

Minnesota Department of Corrections
Offender Grievance

Date: 1-13-15

Offender: RONALDO LIGONS OID: 171203 Living Unit/Cell/Room#: BE 552

Casemanager: MULVEHILL

Instruction to offender – You may add one 8½ X 11 inch sheet of paper to expand your grievance information. You must attach kites, including staff response, showing your attempt to resolve the issue informally and one copy of all supporting exhibits for this grievance. Your grievance will be returned if you do not attach kites.

Grievance: DENIAL OF "SOVALDI" AFTER MEDICATION FOR CURE OF HEPATITIS C. THIS MEDICATION HAS BEEN AVAILABLE FOR MORE THAN A YEAR. IMMEDIATE TREATMENT WITH SOVALDI IS MY REQUEST, WITHOUT DELAY. SEE ATTACHED KITE (RETURN BOTH DOCUMENTS.)

Dist. Original - Facility Grievance Coordinator
Copy - Offender

Date entered _____
Grievance number _____

303.100B (6/2009)

[redacted] Minnesota Department of Corrections

OFFENDER KITE FORM

Offenders are encouraged to communicate with staff at all levels, but it is expected that the chain of command will be used. Your kite should be directed to the staff who can best answer your question. If you send a kite requiring an answer to the wrong staff, it will be returned to you. Kites are to be used for offender to staff correspondence only. If your kite is not specific, it will be returned for additional information. If you want your kite reviewed further up the chain of command, you must attach all previous kites to show the previous responses. HSA - CARES

To: [redacted] Date: 1-1-16

[redacted] LIGONS OID: 171203

Facility/Unit BE Room/Cell 552 Casemanager

Other staff you have contacted regarding this issue and the outcome/decision (attach responses):

PLEASE REPLY AS SOON AS POSSIBLE. -THANX

Issue: TO SATISFY ADM. REMEDIES, I NEED TO HEAR? REQUEST TREATMENT FOR:

A. INFIL FIBERS

B. HCV - TREATMENT WITH SOVALDI OR OTHER MEDICATIONS (ORAL)

Response from: [redacted] **Date:** 1/7/15

I will have to Refer this to the medical staff I do not know where we are with either of them.

[redacted] 1/8/15

Per Dr Duncan @ The new Formulary wait hepc treatment has been denied by Utilization Review and the medical Director three times. Therefore, it cannot be prescribed. (2) All new HCV treatments @ DOC on Hold pending the new Recovery decisions for the new drugs. It will probably be several months before we know.

Distribution upon completion of response: Original to offender; copy to respondent 303.101A (5/2007)

MINNCOR

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Chronic Hepatitis C Management & Procedures

Background

Hepatitis C virus (HCV) infection is a blood borne disease that is more common in prison inmates than in the general population. Nationally, studies have shown that 12-35% of inmates have chronic hepatitis C infection. In the Minnesota Department of Corrections an estimated 10-15% of offenders are chronically infected.

Hepatitis C is most commonly spread by intravenous drug use (IVDU). Unlike other forms of viral hepatitis, the majority of persons (70-80%) who acquire the infection are unable to clear it from their system and become chronically infected. The majority of persons who acquire HCV infection have no symptoms and are unaware of their infection. Blood tests are the only reliable way of detecting HCV infection.

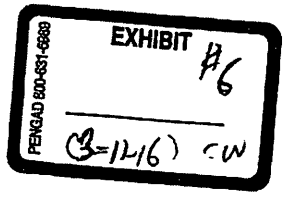
Chronic HCV infection can cause permanent serious liver damage, although this occurs in a minority of cases. When hepatitis C infection causes liver damage, it is generally slow to develop (over years or decades). The majority of cases do not develop serious liver disease, but about 20% of chronically infected persons develop severe liver disease (cirrhosis), which can be fatal. Many chronically infected people do not develop serious liver disease even decades after the initial infection. Other than serial liver biopsies, there are currently no reliable ways to predict who will develop severe disease.

HCV can be treated with antiviral medications that, when effective, can eradicate the hepatitis virus, and, it is hoped, stop the progression of liver disease. These medications are about 50% effective in virus Type 1, the most common type in the USA and the Minnesota Department of Corrections. Treatment is more successful in virus types 2 and 3. The virus is eradicated in about 90% of these cases. The medications used to treat hepatitis C are expensive, have serious, potentially fatal, side effects and toxicities, and require a prolonged course of monitoring and treatment of a minimum of 24 to 48 weeks depending on virus genotype.

In 1999, the Minnesota Department of Corrections, following recommendations of an advisory committee, adopted guidelines for management of Hepatitis C infected offenders. These guidelines were reviewed by a second advisory committee in 2002. Changes recommended by that committee were adopted by the Department that year. Since 1999 the department has evaluated hundreds of offenders for treatment eligibility. Of these, 158 were referred for consideration for liver biopsy to stage their liver disease. As of January 2006, 96 offenders had undergone liver biopsy, 49 of which started antiviral treatment. Treatment response (sustained viral response) on many of these offenders is pending, but the favorable response Sustained Viral Response (SVR) appears similar to what is reported in the medical literature.

The Committee

In February 2006, the Department convened a new Advisory Committee for a series of meetings to review the current guidelines and recommend changes based on new information and past DOC experience. In this process the committee reviewed guidelines and treatment protocols from other correctional agencies, national non-correctional focused hepatitis C management and treatment recommendations, information from medical literature, reports from committee members, and miscellaneous other information. The following guidelines and procedures wer approved by the Committee.



Procedures

A. EDUCATION

The department provides information for all offenders on Hepatitis C during the intake process.

B. SCREENING

1. The department uses the following list of indications from the American Association for the Study of Liver Disease, "Practice Guidelines for Diagnosis, Management and Treatment of Hepatitis C" for determining which offenders should undergo blood testing for the Hepatitis C antibody. Offenders to be screened are those who:
   a. Have a history of intravenous drug use (IVDU)
   b. Received a blood transfusion prior to 1992
   c. Received clotting factors prior to 1987
   d. Have a history of significant blood exposure
   e. Have a persistently increased AST or ALT of unclear cause
   f. Have signs or symptoms of liver disease of unknown cause
   g. Have had hemodialysis
   h. Are or were a sexual partner of a person with HCV infection
   i. Have had unsterile tattoos
   j. Whose mother is infected with HCV

2. The offender may request a medical visit to request one Hepatitis C test per sentence authorized by standing order with input from the medical practitioner. For subsequent tests, the offender must see a practitioner to document the need for another test.

3. The department uses the Hepatitis C antibody as the screening test.

C. IMMUNIZATIONS

1. Hepatitis A and B vaccines will be offered to Hepatitis C positive offenders. These offenders may be screened for immunity before immunization.

2. Pneumococcal vaccine will be offered to offenders with cirrhosis who have not been previously immunized.

D. ANTIVIRAL TREATMENT ELIGIBILITY

1. Antiviral treatment (Interferon) is not approved for use in persons less than 18 years of age. The department does not offer Hepatitis C antiviral treatment to offenders less than 18 years of age.

2. The risks and benefits of Hepatitis C treatment in persons whose life expectancy is limited by advancing age is uncertain especially in those with mild liver disease due to the typically slow progression of Hepatitis C liver disease. The department has established a standard upper age limit of 60 years for treatment eligibility. Treatments for offenders over 60 years old must be approved by the medical director.

3. Hepatitis C treatment is available to offenders regardless of race or gender.

4. Hepatitis C antiviral treatment is prolonged treatment (24 to 48) weeks with significant toxicity and risk that needs to be closely monitored. Interrupting treatment may lead to viral re-emergence (failure of "cure"), and documentation of treatment outcome requires 6 months of after care. Complications and/or side-effects of treatment may result in interruptions in treatment that prolong treatment beyond the standard treatment duration. Due to the associated risks and long-term monitoring needs, the offender must have a remaining duration of confinement of 18 months for Type 1 and 4 Hepatitis C, and 12 months for Type 2 and 3 prior to starting antiviral therapy. The sentence duration requirement may be reviewed on a case-by-case basis where the appropriate continuation and monitoring of treatment in the community can be verified.

5. The majority of offenders, especially those who are chemically dependent, have acquired Hepatitis C through drug use. Successful completion of chemical dependency treatment will eliminate the most common source of reinfection and medical complications. Offenders who are directed to complete chemical dependency treatment by the department must complete this treatment before antiviral therapy begins. The department's medical director may waive this requirement for appropriate indications, such as unavailability of CD treatment at the facility due to the offender's confinement level, life sentences, age, or other unique factors. Chemical dependency treatment will be prioritized for offenders under consideration for Hepatitis C antiviral treatment. In some cases, offenders may be offered a second opportunity for chemical dependency treatment after an initial refusal or failure.

6. Any offender who is unable to stay drug or alcohol free in a controlled environment is unlikely to do so outside and is at a greater risk for reinfection and/or failure of antiviral therapy. Offenders must remain drug and alcohol free (including abuse of prescription medications) for six months prior to starting treatment. Offenders who are undergoing evaluation or receiving treatment for Hepatitis C are screened on a monthly basis for drug use. An offender who tests positive and is disciplined will have a six-month delay in proceeding with the evaluation and will be issued a warning if receiving

treatment. An offender who tests positive twice during treatment will have therapy discontinued.

7. Antiviral Hepatitis C can exacerbate existing mental disorders and precipitate mental disorders in some people. Suicide, although apparently rare during treatment, is reported. All offenders considered for Hepatitis C antiviral treatment will be screened for Axis I mental disorders. If significant mental illness is present, psychiatric review is indicated. Offenders receiving antiviral treatment should undergo initial and monthly depression screening using the Beck depression survey. Offenders who develop mental health symptoms during treatment should be referred to psychiatry for evaluation and possible treatment.

8. The department will review other medical contraindications to Hepatitis C antiviral therapy, including:
   a. Allergy to Ribavirin or Interferon
   b. Decompensated liver disease
   c. Child-Pugh score* > 6 - Persons who have had decompensation may improve to permit treatment.
   d. Clotting Disorder- Usually addressed in Child-Pugh score. Unusual cases evaluated on a case-by-case basis.
   e. Thyroid Disease- Uncontrolled hypo or hyper thyroidism.
   f. Renal Failure- Estimated creatinine clearance < 50 ml/min
   g. Diabetes Mellitus- Poorly controlled Hemoglobin A1C > 9.0
   h. Human Immunovirus Infection: CD4 < 100 cells/microliter or CD4 200-100 cells/microliter and HIV RNA > 5000 copies/microliter
   i. Heart Disease- Functionally significant
   j. Lung Disease- Functionally significant
   k. Organ transplant
   l. Hematologic Abnormalities (baseline): Platelets < 75,000/mm^3, Absolute Neutrophil Count <1500/mm^3, Hemoglobin <12 grams/dl (females), Hemoglobin < 13 grams/dl (males)
   m. Iron Overload- Contraindicated until serum iron is in normal range.
   n. Autoimmune Disorder- Defer treatment until symptoms are stabilized.
   o. Active Psychosis- Significant Depression- If Beck Depression Inventory is >15 treat with antidepressant medication. Prior review by psychiatry is indicated if a history of significant mental illness.
   p. Pregnancy
   q. Behavioral/Adherence- Persons who do not cooperate with recommended monitoring and follow-up care. Persons who do not take the medications as ordered.

E. MONITORING and FOLLOW-UP

* As recommended in American Association for the Study of Liver Disease, "Practice Guidelines for Diagnosis, Management and Treatment of Hepatitis C"

1. Offenders ineligible for treatment are responsible for requesting periodic laboratory follow-up and for reporting and requesting medical follow-up if new symptoms appear.
2. Offenders with advanced liver disease and who are ineligible for anti-viral treatment will receive symptom based medical management.
3. Offenders who complete treatment will be tested for sustained viral response about 24 weeks after completion of treatment with additional monitoring and follow-up based on the result.

F. LIVER BIOPSY

1. Performing a liver biopsy on all offenders with Hepatitis C infection is very low yield in terms of finding individuals with significant liver disease and is prohibitive in terms of community resources and fiscal resources. Transporting up to 15% of DOC offenders for liver biopsy would put a severe strain on department resources and create a public safety risk for what would be low yield in detecting persons with significant liver disease that would not be found by monitoring serial liver enzyme tests. The department will identify and monitor offenders with one abnormal liver enzyme test (elevated enzymes at a reasonable time, approximately three months, after the offender's last opportunity to abuse alcohol or other toxins). Monitoring offenders on a ongoing basis with serial liver enzymes will likely identify nearly all offenders with stage 2, 3 and 4 liver disease, the stages the Committee advises antiviral treatment.

2. The benefits of liver biopsy on persons with type 2 and 3 Hepatitis C virus are questionable in light of the costs due to the 90% SVR rate and the relatively low cost of treatment compared with genotype 1, 4, 5, or 6. The cost of the biopsy is about 50% of treatment cost. A biopsy will not be performed for Type 2 and 3, and treatment will be offered if other criteria are met. Offenders with biopsy state 2, 3 and compensated stage 4 are eligible for antiviral treatment if they meet all other criteria.

3. A biopsy will be performed for Type 1, 4, 5, 6.

4. The department will perform genotype testing on all offenders who test positive for hepatitis C virus by PCR.

G. ANTIVIRAL TREATMENT ADMINISTRATION

1. Genotypes 1, 4, 5, and 6
   Pegylated interferon (Pegasys) and ribavirin based on FDA approved dose for 48 weeks. Test viral load at 12 weeks.
   - o If undetectable, continue treatment for 48 weeks total.
   - o If < 2 log decrease treatment is ineffective, discontinue treatment.

- If 12 week viral load is > 2 log decreasc but still detectable, repeat viral load at 24 weeks. If virus is still detectable discontinue treatment. If repeat viral load is undetectable, continue treatment for 48 weeks total.

2. Genotypes 2 and 3 -HIV negative*
   Interferon alpha-2b and ribavirin for 24 weeks. Test viral load at 12 weeks.
   - If < 2 log decrease discontinue therapy.
   - If > 2 log decrease but virus is still detectable, repeat viral load at 24 weeks. If undetectable at 24 weeks, continue treatment for 48 weeks.
   - If virus is still present at 24 weeks, discontinue therapy

   * Note interferon Alpha-2b is not available at this time. Pegasys is used as standard treatment for these genotypes until further notice.

3. Genotypes 2 and 3 HIV positive
   Interferon alpha-2b and ribavirin for 48 weeks. Test viral load at 12 weeks.
   - If < 2 log decrease discontinue therapy.
   - If > 2 log decrease but virus is still detectable, repeat viral load at 24 weeks. If undetectable at 24 weeks, continue treatment for 48 weeks.
   - If virus is still present at 24 weeks, discontinue therapy

4. Types 2 and 3 who fail to respond to interferon alpha-2b should be evaluated for treatment with Pegylated interferon.

5. DOC preferred interferon for types 1, 4, 5, and 6 is Pegasys for the following reasons: FDA approved for HIV co-infected persons, SVR rate is equivalent to Peg-Intron, Pegasys is preferred on the CMS Formulary, dosing is simpler which is an easier nursing procedure.

6. DOC preferred interferon for types 2 and 3 is Interferon alpha-2b. SVR is nearly the same as with Pegylated interferon and the cost is substantially less.

7. To monitor antiviral treatment, follow manufacturer's recommended schedule for laboratory testing. Offenders should have pretreatment and monthly screen for depression with referral to psychiatry for significant symptoms.

8. Preventive antidepressant use is not recommended. Antidepressants should be used when significant depression symptoms develop or are present prior to onset of treatment.

9. Long-term suppressive HCV anti-viral therapy in treatment failure is a type of investigational treatment that is not FDA approved. No published studies show benefit. This treatment will not be offered to offenders.

10. Studies show that the use of bone marrow stimulating factors to treat HCV treatment-induced anemia or leukopenia can increase neutrophil counts and

hemoglobin in persons treated with interferon and ribavirin and may ameliorate some side effects of treatment. However, there is no medical literature documenting improved sustained viral response with these treatments. Their use should be considered on a case-by-case basis. Treat anemia and neutropenia initially with FDA approved dose reductions. Consider bone marrow stimulation for offenders who have responded to antiviral treatment but are at risk for treatment discontinuation due to severe bone marrow suppression.

Revised January 3, 2011

MINNESOTA DEPARTMENT OF CORRECTIONS
HEALTH SERVICES UNIT

HEPATITIS C (HVC) INFORMATION AND CONSENT FOR EVALUATION AND TREATMENT

171203 9/29/1953

Ligons, Ronaldo Sylvester

	OID Number	Facility FRB

1) I understand that I have hepatitis C (HVC) infection and that blood tests have suggested that there is active disease in my liver. I understand that most people with HCV infection do not develop significant liver disease even after 20 or more years of infection; between 5% and 20% of people with HCV get serious progressive liver disease. I also understand that treatment for HCV can cause many serious side effects and make certain medical conditions worse; it can even lead to death in some cases. I understand that the policy of the Department of Corrections is to offer treatment only if I have progressive permanent liver disease present on liver biopsy or other tests, when my remaining time to be served is greater than the usual treatment and follow-up period, if I am drug and alcohol free as determined by random testing during the period before and during treatment, after I have satisfactorily completed Chemical Dependency (CD) treatment if I am directed to CD treatment by the Department, and if I do not have any medical condition (including recent or serious mental illness) that is a contraindication to treatment. I also understand that if I have a history of poor cooperation with medical, psychiatric, or mental health treatment or evaluation, treatment may be deferred until I show that I will cooperate with these procedures.

Initial RSL WAIVE CD

2) I agree to proceed with further evaluation of my liver with a liver biopsy, if necessary, and further blood tests. I understand that there are certain risks associated with the liver biopsy that include possible allergic reaction to the local anesthetic used to numb my skin, pain at the area where the needle is inserted, possible severe bleeding, and possible injury to my gallbladder or other internal organs. I understand that complications of liver biopsy can be life threatening. I understand that the biopsy will be performed by personnel trained in this procedure, that the biopsy will be performed only if I have normal blood clotting and no fluid accumulation in my abdominal cavity (ascites), and that I will be observed for at least two (2) hours after the biopsy and then be relieved of any work and not do any strenuous activity for the rest of that day and the next.

Initial RSL

3) I understand that if I have significant active damage and scar tissue formation (fibrosis) revealed by my liver biopsy and/or other tests, I might be a candidate for receiving antiviral treatment. I understand that the biopsy and/or other tests might show only a small amount of damage, in which case I would not be offered antiviral treatment. Only those offenders with advanced fibrosis are offered treatment.

Initial RSL

4) I understand that HCV medications have side effects. No single medication is effective to treat HCV; combinations of two or more medications are required. The choice of the medications and duration of treatment is based on several factors primarily the genotype (subtype) of the virus, my past history of HCV treatment, severity of fibrosis, and other medical condition(s).

Initial RSL

5) I understand that no promises was made to me that I will receive HCV treatment after the liver biopsy and other tests. I also understand that if I do receive HCV treatment, the treatment may not eliminate the HCV or prevent cirrhosis of the liver or prevent the development of liver cancer.

Initial RSL

EXHIBIT #7 (3/1/16) CW

PENGAD 800-631-6989

MINNESOTA DEPARTMENT OF CORRECTIONS
HEALTH SERVICES UNIT

171203 9/29/1953

Ligons, Ronaldo Sylvester

	OID Number	Facility FRB

6) I understand that if the Department of Corrections directs me to CD treatment, I must satisfactorily complete this treatment prior to liver biopsy or HCV treatment. In certain situations. Including the presence of advanced fibrosis, the Department may waive the CD treatment requirement. I understand that I will be randomly tested for illegal drugs and alcohol prior to and during hepatitis C treatment. If I test positive or if I refuse the tests, therapy will be stopped.

Initial RSL WAIVE CD

7) I understand that ribavirin causes birth defects. If I am a woman, I must not become pregnant while taking ribavirin and for six (6) months after I stop taking it. If I am a man, I must not make a woman pregnant while I am taking ribavirin and for six (6) months after I stop taking it.

Initial RSL

8) I understand that after treatment is started, tests will be done to monitor the effectiveness and side effects of treatment, and that treatment may be stopped if determined to be ineffective or for significant side effects. The test to determine treatment effectiveness is the viral load test, which goes to undetectable levels if treatment is effective. If I do not cooperate with treatment, including taking the medication as prescribed and testing or monitoring during treatment, the treatment will be stopped.

Initial RSL

9) I have discussed by my medical practitioner risks/benefits of having a liver biopsy and receiving HCV treatment. All my questions have been answered in terms and language that I understand. If I have additional questions opportunities for further discussion are available.

Initial RSL

10) I understand that I may withdraw my consent for liver biopsy, testing and treatment at any time. If I do not consent at this time, I can change my mind and be considered for evaluation and treatment in the future.

Initial RSL

	I agree to have further evaluation of my Hepatitis C with a liver biopsy, laboratory testing, and psychological and medical follow-up if indicated,
	I decline further evaluation of my HCV infection.

Offender Signature RSL	Date 4-10-15
Practitioner Signature [illegible]	Date 4-10-15

3/27/2015

Central Office
1450 Energy Park Drive Suite 200 • St. Paul MN, 55108
PH651.361.7200 • Fax 651-642-0223 • TTY800.627.3529
www.doc.state.mn.us

DATE: January 31, 2016

TO: All Offenders

FROM: Health Services

SUBJECT: Diagnostic Testing

The MN Department of Corrections (DOC) as well as public health entities recommend testing for RPR (Syphilis) and HIV (Human Immunodeficiency Virus).

- You have the right to opt out (decline) testing.
- If you choose to decline, please inform the staff that you choose to not be tested for RPR or HIV.

In addition, the Department will provide one test for Hepatitis C at your request during each DOC admission. For additional HCV or HIV tests, you will need to see a clinician to get a specific order for the test.

The risk factors below have been identified by the Centers for Disease Control (CDC). If you have any of these risk factors, the DOC as well as public health entities, recommend that you get tested for **Hepatitis C and HIV**.

If you answer yes to any of these questions, the DOC recommends you request testing.

- Were you born between 1945 and 1965?
- Did you have a blood transfusion or organ transplant (get blood or organs from someone else) before 1992?
- Have you ever injected drugs (except prescription drugs such as insulin)?
- Do you have chronic liver disease, HIV or AIDS?
- Have you had tattoos or body piercing at an un-licensed business?

Please indicate during your intake physical that you would like to be tested, or send a kite request to Health Services.

EXHIBIT 8 3-11-16 CW
PENGAD 800-631-6989

HEPATITIS C & INCARCERATION

What is hepatitis?

"Hepatitis" means inflammation or swelling of the liver. The liver is an important organ that helps the body digest food, clean blood, and fight germs. When the liver is inflamed or damaged, it does not work very well.

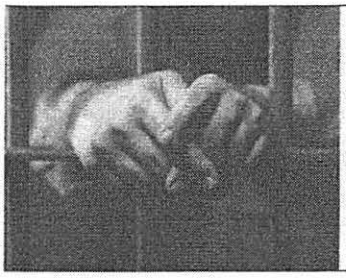
Hepatitis is most often caused by a virus. There are three common types of viral hepatitis: Hepatitis A, Hepatitis B, and Hepatitis C. They are all different from each other and are spread from one person to another in different ways. Hepatitis C is the most common type of hepatitis in the United States. It is also the most common type in jails and prisons.

What is Hepatitis C?

Hepatitis C is a serious liver disease that is caused by the Hepatitis C virus. Hepatitis C is called a silent disease because people can get infected and not know it. Some people who get infected with Hepatitis C are able to clear, or get rid of the virus. For most people who get Hepatitis C, the virus stays in their body for life. Doctors call this chronic Hepatitis C.

Incarceration and Hepatitis C

- Hepatitis C can be a health problem for people who have been incarcerated.
- Adults in correctional facilities are at risk for Hepatitis C because many people in jails or prisons already have Hepatitis C.
- The most common way inmates get Hepatitis C is by sharing equipment used for injecting drugs, tattooing, and piercing with other people who are already infected.
- The Hepatitis C virus can be spread easily to others through blood, even in very small amounts too small to see.



There are about 2.2 million people in US jails and prisons. 1 in 3 have Hepatitis C.

How is Hepatitis C spread?

Hepatitis C is most often spread when blood from a person who has Hepatitis C enters the body of someone who is not infected. Here are common ways someone can get Hepatitis C:

Blood: The Hepatitis C virus can be found in blood spills, droplets, and blood splatters outside the body. The virus can survive in dried blood for several days. Whenever contact is made with surfaces, equipment, or objects that have infected blood on them—even in amounts too small to see—the virus can be spread to others.

Drugs: Most people get the Hepatitis C virus from an infected person when sharing needles or other equipment to inject drugs. Even tiny amounts of blood on needles and other types of drug equipment can spread Hepatitis C from one person to another.

Tattoos/Piercing/Scarring: The Hepatitis C virus can be spread when tattoo, body art, or piercing equipment has tiny amounts of blood on it. Many people get tattoos, piercings, or other marks while incarcerated. When they share the equipment, it is easy for people to spread the virus and become infected with Hepatitis C.

Sex: The Hepatitis C virus can be spread through sex, although this does not happen very often. The virus seems to be more easily spread through sex when a person also has HIV or an STD. People who have rough sex or many sex partners seem to get Hepatitis C more often.

U.S. Department of Health and Human Services
Centers for Disease

Continued on next page

Can Hepatitis C be prevented?

Yes. To prevent Hepatitis C:

- Do not use tattooing, piercing, or cutting equipment that has been used on someone else. This includes such things as sharp objects, ink, needles, or barrels that could have even tiny amounts of blood on them that are too small to see.
- Do not share needles or other equipment, including cookers, cottons, ties, or water to inject drugs.
- Do not share razors, toothbrushes, or other personal items that may have come into contact with another person's blood.

Why doesn't cleaning kill the Hepatitis C virus?
Bleaching, boiling, heating with a flame, or using common cleaning fluids, alcohol, or peroxide will **not** clean needles, tools, and other instruments. These methods are not strong enough to kill the Hepatitis C virus. The virus can still spread easily from one person to another.

How can you tell if someone has Hepatitis C?

You cannot tell if someone has Hepatitis C by looking at them. Doctors use a blood test to look for "antibodies," or signs in a person's blood, that they have been infected with the Hepatitis C virus at some point in time. If this test is positive for Hepatitis C antibodies, a different blood test is needed. The second test will tell if the Hepatitis C virus is still in the body. If this test is positive, it means a person currently has Hepatitis C. Additional tests and a medical exam are needed to confirm the diagnosis.

What are the symptoms of Hepatitis C?

Many people with Hepatitis C have no symptoms and do not know they are infected. If a person has symptoms, they can include one or more of the following: fever, stomach pain, feeling very tired, grey-colored stool, not wanting to eat, bone or joint pain, upset stomach, throwing up, dark urine, yellow skin and eyes.

What happens if a person has Hepatitis C?

When a person gets infected with the Hepatitis C virus, different things can happen depending on a person's age, health, and use of drugs or alcohol. Some people have health problems within a few years of getting infected. Other people live with Hepatitis C for 20 or 30 years without symptoms or feeling sick. Over time, the virus can cause serious health problems for some people.

Can Hepatitis C be treated?

Yes, but not everyone needs medical treatment or can benefit from it. If possible, it is important for people who have Hepatitis C to get regular check-ups. A doctor will run tests to see if the virus is causing damage to the liver. If the liver is damaged, medicines called "antivirals" can sometimes help. These medicines can slow damage to the liver, and may even get rid of the virus.

What can people infected with Hepatitis C do to take care of their liver?

People with Hepatitis C should not use alcohol or street drugs, as these can hurt the liver. Some other products can also hurt people with Hepatitis C, even if they appear to be safe. Check with medical staff before taking any kind of pill, vitamin, herbal product, or medicine.

For more information

Talk to medical staff or your doctor, or have your loved ones talk to a doctor, clinic, or health department. Information on Hepatitis C can be found at: www.cdc.gov/hepatitis.

Publication No. 21-1306

Guidelines for Evaluation and Management of Chronic Hepatitis C (HCV) Infection

The purpose of these guidelines is to provide guidance to health services staff about screening and testing offenders to determine whether they have a chronic hepatitis C virus (HCV) infection; evaluating HCV infected offenders for treatment with antiviral agents; and monitoring the condition of HCV infected offenders during and after treatment. These guidelines will be updated periodically in accordance with treatment recommendations by nationally recognized authorities, such as the American Association for the Study of Liver Disease (AASLD), are revised.

1. Intake Screening for Risk of HCV Infection

At intake, DOC staff will:

a. Explain the HCV risk factors to offenders and recommend that offenders request blood testing if they have any of the risk factors;

b. Provide education information on transmission, development and potential impact of chronic HCV infection, what HCV testing involves, and how chronic HCV infection is managed and treated; and

c. Explain procedures for requesting HCV blood test.

2. Blood Testing for HCV

Blood testing for HCV includes a screening blood test for the HCV antibody and, if that test is positive, a confirmatory test to determine whether there is active infection (HCV RNA).

a. All HCV blood testing is voluntary.

b. HCV blood tests may be requested by an offender or ordered by a practitioner.

c. Offenders who request HCV blood testing will not be charged a co-pay or be required to disclose the presence of any risk factor(s).

3. Evaluating HCV Infected Offenders

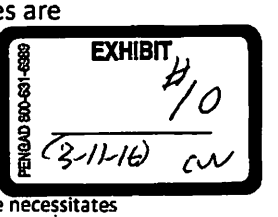
Offenders determined to have an active infection (HCV RNA positive) will have an initial evaluation and periodic evaluations to determine what treatment, if any, is required and when.

a. Initial Evaluation

Practitioners at each facility will conduct an initial evaluation that includes:

1) targeted history and physical exam;

2) laboratory testing, such as liver profile, complete blood count (CBC), and HCV genotype, and any other tests the practitioner determines are indicated;



3) immunization for hepatitis A and B or testing for immunity for these diseases, if indicated;
4) explanation of the process for periodic evaluation and criteria for determining treatment eligibility; and
5) providing the offender with written instructions about how frequently the offender should arrange for periodic evaluations.

b. Periodic Evaluation of Chronic Infection
Because chronic HCV infection can cause liver damage, offenders identified as HCV RNA positive should be evaluated periodically to monitor the progression of the disease.

1) Offenders must arrange for periodic evaluations of their condition in accordance with the written instructions provided by the practitioner who completed the initial evaluation; must follow procedures at the facility where they reside to request a periodic evaluation; and will not be charged a co-payment for periodic evaluations.
2) Practitioners at the facilities will conduct the periodic evaluations, which will generally consist of:
   a) an interim targeted history and physical exam;
   b) lab testing, CBC, and liver profile;
   c) other testing as clinically indicated, including blood test panel to determine liver fibrosis (e.g. Fibrotest or Fibrosure); basic metabolic panel (BMP); abdominal ultrasound or alternative imaging studies (e.g. Fibroscan); or liver biopsy

c. Practitioners and/or facility staff will complete a Hepatitis C Case Report after the initial evaluation and an updated Hepatitis C Case Report after each periodic evaluation and send the report and results of all related lab tests to the DOC medical director.

4. Approving Anti-viral Treatment

Based on the updated Hepatitis C Case Reports and additional clinical information, the DOC Medical Director or designee may authorize patient-specific antiviral treatment.

a. Only FDA approved medications will be used for HCV treatment.
b. Generally, the DOC Medical Director will approve anti-viral treatment for offenders with advanced fibrosis (stage 3-4); or for offenders with mild fibrosis (stage 2) who have concurrent hepatitis B or HIV infection or end organ damage caused by HCV infection.
c. Treatment regimens approved will be consistent with current treatment recommendations established by a nationally recognized authority, such as the American Association for the Study of Liver Disease (AASLD), and patient-specific factors, such as genotype, HCV viral load, disease stage, co-existing medical

conditions, medication interactions (real or possible), time remaining on term of imprisonment, and compliance with previous medical treatment.

d. Treatment will not be approved for those with terminal conditions or known allergy or previous serious adverse reaction to one or more of the treatment medications.

e. Treatment may be deferred if an offender has a recent history of non-adherence to medical monitoring or medication treatment, recent documented illicit drug or alcohol use while in the prison system, and unstable medical condition that may impact the continuity of treatment (such as a planned surgery) or may impact the outcome of anti-viral treatment.

f. HCV anti-viral treatment will be administered as directly observed therapy by nursing staff.

5. Monitoring During and After Anti-viral Treatment

Practitioners at the facility will monitor to ensure that offenders who are receiving anti-viral treatment are complying with their treatment regimens and to determine the effectiveness of the treatment.

a. *Practitioners will obtain lab tests prior to and during treatment weeks, as* established by the lab monitoring guidelines.

b. Practitioners will report to the Medical Director all information related to the effectiveness of antiviral treatment, including such examples as:

1) the offender is not complying with the treatment regimen, clinical monitoring or lab testing;

2) the offender has a significant adverse or allergic reaction to a medication that cannot be managed medically;

3) laboratory tests reveal evidence of treatment failure based on continued presence of HCV virus in the blood; or

4) evidence of illicit drug or alcohol use during treatment.

January 19, 2016

HPP EX. 1

325 Cedar St., Ste. 308, St. Paul, MN 55101

WHEN AND IN WHOM TO INITIATE HCV THERAPY

Successful hepatitis C treatment results in sustained virologic response (SVR), which is tantamount to virologic cure, and as such, is expected to benefit nearly all chronically infected persons. When the US Food and Drug Administration (FDA) approved the first IFN-sparing treatment for HCV infection, many patients who had previously been "warehoused" sought treatment, and the infrastructure (experienced practitioners, budgeted health-care dollars, etc) did not yet exist to treat all patients immediately. Thus, the panel offered guidance for prioritizing treatment first to those with the greatest need. Since that time, there have been opportunities to treat many of the highest-risk patients and to accumulate real-world experience of the tolerability and safety of newer HCV medications. More importantly, from a medical standpoint, data continue to accumulate that demonstrate the many benefits, within the liver and extrahepatic, that accompany HCV eradication. Therefore, the panel continues to recommend treatment for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Accordingly, prioritization tables are now less useful and have been removed from this section.

Despite the strong recommendation for treatment for nearly all HCV-infected patients, pretreatment assessment of a patient's understanding of treatment goals and provision of education on adherence and follow-up are essential. A well-established therapeutic relationship between practitioner and patient remains crucial for optimal outcomes with new direct-acting antiviral (DAA) therapies. Additionally, in certain settings there remain factors that impact access to medications and the ability to deliver them to patients. In these settings, practitioners may still need to decide which patients should be treated first. The descriptions below of unique populations may help physicians make more informed treatment decisions for these groups. (See Unique Patient Populations: Patients with HIV/HCV Coinfection [1], Unique Patient Populations: Patients with Decompensated Cirrhosis [2], Unique Patient Populations: Patients who Develop Recurrent HCV Infection Post-liver Transplantation [3], and Unique Patient Populations: Patients with Renal Impairment [4]).

Expansions and notes for abbreviations used in this section can be found in Methods Table 3 [5].

A summary of recommendations for When and in Whom to Initiate HCV Therapy is found in the BOX [6].

Goal of Treatment

- The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.

  Rating: Class I, Level A

Recommendations for When and in Whom to Initiate Treatment

- Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.

  Rating: Class I, Level A

Clinical Benefit of Cure

The proximate goal of HCV therapy is SVR (virologic cure), defined as the continued absence of detectable HCV RNA at least 12 weeks after completion of therapy. SVR is a marker for cure of HCV infection and has been shown to be durable, in large prospective studies, in more than 99% of patients followed up for 5 years or more. (Swain, 2010 [7]); (Manns, 2013 [8]) Patients in whom an SVR is achieved have HCV antibodies but no longer have detectable HCV RNA in serum, liver tissue, or mononuclear cells, and achieve substantial improvement in liver histology. (Marcellin, 1997 [9]); (Coppola, 2013 [10]); (Garcia-Bengoechea, 1999 [11]) Assessment of viral response, including documentation of SVR, requires use of an FDA-approved quantitative or qualitative nucleic acid test (NAT) with a detection level of 25 IU/mL or lower.

Patients who are cured of their HCV infection experience numerous health benefits, including a decrease in liver inflammation as reflected by improved aminotransferase (ie, alanine aminotransferase [ALT], aspartate aminotransferase [AST]) levels and a reduction in the rate of progression of liver fibrosis. (Poynard, 2002b [12]) Of 3010 treatment-naive HCV-infected patients with pretreatment and posttreatment biopsies from 4 randomized trials of 10 different IFN-based regimens (biopsies separated by a mean of 20 months), 39% to 73% of patients who achieved an SVR had improvement in liver fibrosis and necrosis (Poynard, 2002b [12]), and cirrhosis resolved in half of the cases. Portal hypertension, splenomegaly, and other clinical manifestations of advanced liver disease also improved. Among HCV-infected persons, SVR is associated with a more than 70% reduction in the risk of liver cancer (hepatocellular carcinoma [HCC]) and a 90% reduction in the risk of liver-related mortality and liver transplantation. (Morgan, 2013 [13]); (van der Meer, 2012 [14]); (Veldt, 2007 [15])

Cure of HCV infection also reduces symptoms and mortality from severe extrahepatic manifestations, including cryoglobulinemic vasculitis, a condition affecting 10% to 15% of HCV-infected patients. (Fabrizi, 2013 [16]); (Landau, 2010 [17]); (Isse, 2010 [18]) HCV-infected persons with non-Hodgkin lymphoma and other lymphoproliferative disorders achieve complete or partial remission in up to 75% of cases following successful therapy for HCV infection. (Gisbert, 2005 [19]); (Takahashi, 2012 [20]); (Svoboda, 2005 [21]);

(Mazzaro, 2002 [22]); (Hermine, 2002 [23]) These reductions in disease severity contribute to dramatic reductions in all-cause mortality. (van der Meer, 2012 [14]); (Backus, 2011 [24]) Lastly, patients who achieve SVR have substantially improved qualities of life, which include physical, emotional, and social health. (Boscarino, 2015 [25]); (Neary, 1999 [26]); (Younossi, 2013 [27]) Because of the many benefits associated with successful HCV treatment, clinicians should treat HCV-infected patients with antiviral therapy with the goal of achieving an SVR, preferably early in the course of chronic HCV infection before the development of severe liver disease and other complications.

Benefits of Treatment at Earlier Fibrosis Stages (Metavir Stage Below F2)

Initiating therapy in patients with lower-stage fibrosis augments the benefits of SVR. In a long-term follow-up study, 820 patients with Metavir stage F0 or F1 fibrosis confirmed by biopsy were followed up for up to 20 years. (Jezequel, 2015 [28]) The 15-year survival rate was statistically significantly better for those who experienced an SVR than for those whose treatment had failed or for those who remained untreated (93%, 82%, and 88%, respectively; $P = .003$). The study results argue for consideration of earlier initiation of treatment. Several modeling studies also suggest a greater mortality benefit if treatment is initiated at fibrosis stages prior to F3. (Øvrehus, 2015 [29]); (Zanno, 2015 [30]); (McCombs, 2015 [31])

Treatment delay may decrease the benefit of SVR. In a report of long-term follow-up in France, 820 patients with biopsy-confirmed Metavir stage F0 or F1 fibrosis were followed up for as long as 20 years. (Jezequel, 2015 [28]) The authors noted rapid progression of fibrosis in 15% of patients during follow-up, and in patients treated successfully, long-term survival was better. Specifically, at 15 years, survival rate was 92% for those with an SVR versus 82% for treatment failures and 88% for those not treated. In a Danish regional registry study, investigators modeled treatment approaches with the aim of evaluating the benefit to the region in terms of reductions in morbidity and mortality and HCV prevalence. (Øvrehus, 2015 [29]) Although they note that in their situation of low HCV prevalence (0.4%), with approximately 50% undiagnosed, a policy that restricts treatment to those with Metavir fibrosis stage F3 or higher would decrease mortality from HCC and cirrhosis, the number needed to treat to halve the prevalence of the disease is lower if all eligible patients receive treatment at diagnosis. A modeling study based on the Swiss HIV Cohort Study also demonstrated that waiting to treat HCV infection at Metavir fibrosis stages F3 and F4 resulted in 2- and 5-times higher rates of liver-related mortality, respectively, compared with treating at Metavir stage F2. (Zanno, 2015 [30])

A US Veterans Administration dataset analysis that used very limited end points of virologic response dating from the IFN-treatment era suggested that early (at a Fibrosis-4 [FIB-4] score of <3.25) initiation of therapy increased the benefit attained with respect to likelihood of treatment success and mortality reduction and ultimately decreased the number of patients needed to treat to preserve 1 life by almost 50%. (McCombs, 2015 [31])

Considerations in Specific Populations

Despite the recommendation for treatment of nearly all patients with HCV infection, it remains important for clinicians to understand patient- and disease-related factors that place individuals at risk for HCV-related complications (liver and extrahepatic) as well as for HCV transmission. Although these groups are no longer singled out for high prioritization for treatment, it is nonetheless important that practitioners recognize the unique dimensions of HCV disease and its natural history in these populations. The discussions offered below may assist clinicians in making compelling cases for insurance coverage of

treatment when necessary.

Persons With Advanced Liver Disease

For persons with advanced liver disease (Metavir stage F3 or F4), the risk of developing complications of liver disease such as hepatic decompensation (Child Turcotte Pugh [CTP] Class B or C [32] [Methods Table 3 [5]]) or HCC is substantial and may occur in a relatively short timeframe. A large prospective study of patients with cirrhosis resulting from HCV infection examined the risk of decompensation, including HCC, ascites, jaundice, bleeding, and encephalopathy, and found that the overall annual incidence rate was 3.9%. (Sangiovanni, 2006 [33]) The National Institutes of Health (NIH)-sponsored HALT-C study included a group of 220 patients with cirrhosis resulting from HCV infection who were observed for approximately 8 years. A primary outcome of death, hepatic decompensation, HCC, or increase in CTP score of 2 or higher occurred at a rate of 7.5% per year. (Everson, 2006 [34]); (Di Bisceglie, 2008 [35]) Patients with a CTP score of 7 or higher experienced a death rate of 10% per year.

Numerous studies have demonstrated that hepatitis C therapy and the achievement of an SVR in this population results in dramatic decreases in hepatic decompensation events, HCC, and liver-related mortality. (Morgan, 2013 [13]); (van der Meer, 2012 [14]); (Backus, 2011 [24]); (Dienstag, 2011 [36]); (Berenguer, 2009 [37]); (Mira, 2013 [38]) In the HALT-C study, patients with advanced fibrosis secondary to HCV infection who achieved an SVR, compared with patients with similarly advanced liver fibrosis who did not achieve an SVR, had a decreased need for liver transplantation (hazard ratio [HR], 0.17; 95% confidence interval [CI], 0.06–0.46), decreased development of liver-related morbidity and mortality (HR, 0.15; 95% CI, 0.06–0.38) and decreased HCC (HR, 0.19; 95% CI, 0.04–0.80). (Dienstag, 2011 [36]) Importantly, persons with advanced liver disease also require long-term follow-up and HCC surveillance regardless of treatment outcome (see **Monitoring Patients who are Starting Hepatitis C Treatment, are on Treatment, or have Completed Therapy** [39]).

Given the clinical complexity and the need for close monitoring, patients with advanced liver disease that has already decompensated (CTP Class B or C [32] [Methods Table 3 [5]]) should be treated by physicians with experience in treating HCV in conjunction with a liver transplantation center if possible (see Unique Patient Populations: Patients with Decompensated Cirrhosis [2]).

Persons Who Have Undergone Liver Transplantation

In HCV-infected individuals, HCV infection of the liver allograft occurs universally in those with viremia at the time of transplantation. Histologic features of hepatitis develop in about 75% of recipients in the first 6 months following liver transplantation. (Neumann, 2004 [40]) By the fifth postoperative year, up to 30% of untreated patients have progressed to cirrhosis. (Neumann, 2004 [40]); (Charlton, 1998 [41]) A small proportion of patients (4%-7%) develop an accelerated course of liver injury (cholestatic hepatitis C, associated with very high levels of viremia) with subsequent rapid allograft failure. Recurrence of HCV infection posttransplantation is associated with decreased graft survival for recipients with HCV infection compared to recipients who undergo liver transplantation for other indications. (Forman, 2002 [42])

Effective HCV therapy pretransplantation resulting in an SVR (virologic cure) prevents HCV recurrence posttransplantation. (Everson, 2003 [43]) In addition, complete HCV viral suppression prior to transplantation prevents recurrent HCV infection of the graft in the majority of cases. (Forns, 2004 [44]); (Everson, 2005 [45]) Preliminary data from a study of patients with complications of cirrhosis secondary to HCV infection, who were wait-listed for liver transplantation, that included patients with MELD scores up to 14 and CTP scores up to 8 found that treatment with sofosbuvir and weight-based RBV for up to 48

weeks was well tolerated and was associated with an overall posttransplant SVR rate of 70%. (Curry, 2015 [46]) Posttransplant SVR was nearly universal among patients who had undetectable HCV RNA for 28 days or longer prior to transplantation.

Treatment of established HCV infection posttransplantation also yields substantial improvements in patient and in graft survival. (Berenguer, 2008 [47]); (Picciotto, 2007 [48]) The availability of effective IFN-free HCV treatments has addressed the major hurdles to treating HCV recurrence posttransplantation: poor tolerability and efficacy. In a multicenter, open-label study that evaluated the ability of sofosbuvir plus RBV to induce virologic suppression in 40 patients post-liver transplant with compensated recurrence of HCV infection, daily sofosbuvir and RBV for 24 weeks achieved an SVR at 12 weeks (SVR12) in 70%. (Charlton, 2015 [49]) No deaths, graft losses, or episodes of rejection occurred. Six patients had serious adverse events, all of which were considered unrelated to study treatment. There were no drug interactions reported between sofosbuvir and any of the concomitant immunosuppressive agents. In contrast, treatment with sofosbuvir plus RBV with or without PEG-IFN in 64 patients with severe, decompensated cirrhosis resulting from recurrence of HCV infection following liver transplantation was associated with an overall SVR12 rate of 59% and a mortality rate of 13%. (Forns, 2015 [50]) On an intent-to-treat basis, treatment was associated with clinical improvement in 57% and stable disease in 22% of patients. Given the clinical complexity including drug interactions and the need for close monitoring, patients with liver transplant should be treated by physicians with experience in treating this population (see Unique Patient Populations: Patients who Develop Recurrent HCV Infection Post Liver Transplantation [51]).

Persons at Greater Risk for Rapidly Progressive Fibrosis and Cirrhosis

Fibrosis progression is variable across different patient populations as well as within the same individual over time. Many of the components that determine fibrosis progression and development of cirrhosis in an individual are unknown. However, certain factors, such as coinfection with HIV or hepatitis B virus (HBV) and prevalent coexistent liver diseases (eg, nonalcoholic steatohepatitis [NASH]), are well-recognized contributors to accelerated fibrosis progression.

HIV coinfection. HIV coinfection accelerates fibrosis progression among HCV-infected persons. (Benhamou, 1999 [52]); (Macias, 2009 [53]), (Konerman, 2014 [54]) although control of HIV replication and restoration of CD4+ cell counts may mitigate this to some extent. (Bennamou, 2001 [55]); (Brau, 2006 [56]) However, antiretroviral therapy is not a substitute for HCV treatment. In the largest paired-biopsy study, 282 HIV/HCV-coinfected patients with 435 paired biopsies were prospectively evaluated, (Konerman, 2014 [54]) one-third of patients showed fibrosis progression of at least one Metavir stage at a median of 2.5 years. Importantly, 45% of patients with no fibrosis on initial biopsy had progression. Finally, a more rapid progression to death following decompensation combined with a lack of widespread access to liver transplantation and poor outcomes following transplantation highlight the need for treatment in this population regardless of current fibrosis stage (see Unique Patient Populations: Patients with HIV/HCV Coinfection [1]). (Pineda, 2005 [57]); (Merchante, 2006 [58]); (Terrault, 2012 [59])

HBV coinfection and other coexistent liver diseases. The prevalence of HBV/HCV coinfection is estimated at 1.4% in the United States and 5% to 10% globally. (Tyson, 2013 [60]); (Cruz, 2006 [61]) Persons with HBV/HCV coinfection and detectable viremia of both viruses are at increased risk for disease progression, decompensated liver disease, and the development of HCC.

HBV/HCV coinfected individuals are susceptible to a process called viral interference wherein one virus

may interfere with the replication of the other virus. Thus, when treating one or both viruses with antiviral drugs, periodic retesting of HBV DNA and HCV RNA levels during and after therapy is prudent, particularly if only one of the viruses is being treated at a time. Treatment of HCV infection in such cases utilizes the same genotype-specific regimens as are recommended for HCV monoinfection **(see Initial Treatment of HCV Infection [62])**. HBV infections in such cases should be treated as recommended for HBV monoinfection. (Lok, 2009 [63])

Persons with other chronic liver diseases who have coincident chronic HCV infection should be considered for hepatitis C therapy, given the potential for rapid progression of liver disease. An IFN-free regimen is generally preferred for immune-mediated liver diseases such as autoimmune hepatitis, because of the potential for IFN-related exacerbation.

Persons With Extrahepatic Manifestations of Chronic HCV Infection

Severe renal impairment. Chronic hepatitis C is associated with a syndrome of cryoglobulinemia and an immune complex and lymphoproliferative disorder that produces arthralgias, fatigue, palpable purpura, renal disease (eg, membranoproliferative glomerulonephritis), neurologic disease (eg, peripheral neuropathy, central nervous system vasculitis), and reduced complement levels. (Agnello, 1992 [64]) Because patients with chronic hepatitis C frequently have laboratory evidence of cryoglobulins (more than 50% in some series), antiviral treatment is imperative for those with the syndrome of cryoglobulinemia and symptoms or objective evidence of end-organ manifestations. IFN-based regimens can produce clinical remission, however, the adverse effects of IFN may mimic manifestations of cryoglobulinemia. (Saadoun, 2011 [65]) Although clinical data are not yet available, the use of IFN-free DAA regimens is an attractive option for these patients. Organ-threatening disease (eg, severe neuropathy, renal failure, digital ischemia), in addition to antiviral HCV therapy, should be treated more acutely with immunosuppressive agents or plasmapheresis to clear immune complexes.

Glomerular disease results from deposition of HCV-related immune complexes in the glomeruli. (Johnson, 1993 [66]) Successful treatment of HCV using IFN-based regimens can reverse proteinuria and nephrotic syndrome but usually does not fully ameliorate azotemia. (Johnson, 1994 [67]) No clinical trial data are yet available on IFN-free regimens, but the high rates of SVR (virologic cure) with antiviral therapy support their use in management of hepatitis C-related renal disease and cryoglobulinemia.

Nonhepatic Manifestations of Chronic HCV Infection

The relationship between chronic hepatitis C and diabetes (most notably type 2 diabetes and insulin resistance) is complex and incompletely understood. The prevalence and incidence of diabetes is increased in the context of hepatitis C. (White, 2008 [68]) In the United States, type 2 diabetes occurs more frequently in HCV-infected patients, with a more than 3-fold greater risk in persons older than 40 years. (Mehta, 2000 [69]) The positive correlation between quantity of plasma HCV RNA and established markers of insulin resistance confirms this relationship. (Fonseca, 2007 [70]) Insulin resistance and type 2 diabetes are independent predictors of a more rapid progression of liver fibrosis and an impaired response to IFN-based therapy. (Petta, 2008 [71]) Patients with type 2 diabetes and insulin resistance are also at increased risk for HCC. (Huang, 2011 [72])

Successful antiviral treatment has been associated with improved markers of insulin resistance and greatly reduced incidence of new onset of type 2 diabetes and insulin resistance in HCV-infected patients. (Romero-Gómez, 2009 [73]) Most recently, antiviral therapy for HCV infection has been shown to improve clinical outcomes related to diabetes. In a large prospective cohort from Taiwan, the incidence rates of

end-stage renal disease, ischemic stroke, and acute coronary syndrome were greatly reduced in HCV-infected patients with diabetes who received antiviral therapy compared with untreated, matched controls. (Hsu, 2014 [74]) Therefore, antiviral therapy may prevent progression to diabetes in patients with prediabetes who have hepatitis C and may reduce renal and cardiovascular complications in patients with established diabetes who have hepatitis C.

In patients with chronic hepatitis C, fatigue is the most frequently reported symptom and has a major effect on quality of life and activity level evidenced by numerous measures of impaired quality of life. (Foster, 1998 [75]) The presence and severity of fatigue appears to correlate poorly with disease activity, although it may be more common and severe in HCV-infected individuals with cirrhosis. (Poynard, 2002a [76]) Despite difficulties in separating fatigue symptoms associated with hepatitis C from those associated with other concurrent conditions (eg, anemia, depression), numerous studies have reported a reduction in fatigue after cure of HCV infection. (Bonkovsky, 2007 [77]) In the Virahep-C study, 401 patients with HCV infection were evaluated for fatigue prior to and after treatment, using validated scales to assess the presence and severity of fatigue. (Sarkar, 2012 [78]) At baseline, 52% of patients reported having fatigue, which was more frequent and severe in patients with cirrhosis than in those without cirrhosis. Achieving an SVR was associated with a substantial decrease in frequency and severity of fatigue. A recent analysis of 413 patients from the NEUTRINO and FUSION trials who were treated with a sofosbuvir-containing regimen and who achieved an SVR12 demonstrated improvement in patient fatigue (present in 12%) from the pretreatment level. (Younossi, 2014 [79]) After achieving an SVR12, participants had marked improvements in fatigue over their pretreatment scores measured by 3 separate validated questionnaires. Additional studies support and extend these findings beyond fatigue, with improvements in overall health-related quality of life and work productivity observed following successful HCV therapy.(Gerber, 2015 [80]); (Younossi, 2015b [81]); (Younossi, 2015c [82]); (Younossi, 2015d [83])

The reported prevalence of HCV infection in patients with porphyria cutanea tarda approximates 50% and occurs disproportionately in those with cirrhosis. (Gisbert, 2003 [84]) The treatment of choice for active porphyria cutanea tarda is iron reduction by phlebotomy and maintenance of a mildly iron-reduced state without anemia. However, although improvement of porphyria cutanea tarda during HCV treatment with IFN has frequently been described (Takikawa, 1995 [85]), there are currently insufficient data to determine whether treating HCV infection with DAAs and achievement of SVR improve porphyria cutanea tarda.

Lichen planus is characterized by pruritic papules involving mucous membranes, hair, and nails. Antibodies to HCV are present in 10% to 40% of patients with lichen planus, but a causal link with chronic infection is not established. Resolution of lichen planus has been reported with IFN-based regimens, but there have also been reports of exacerbation of lichen planus with these treatments. Although it is unknown whether DAAs will have more success against lichen planus, treatment with IFN-free regimens would appear to be a more advisable approach to addressing this disorder. (Gumber, 1995 [86])

Benefit of Treatment to Reduce Transmission

Persons who have successfully achieved an SVR (virologic cure) no longer transmit the virus to others. As such, successful treatment of HCV infection benefits public health. Several health models have shown that even modest increases in successful treatment of HCV infection among persons who inject drugs can decrease prevalence and incidence. (Martin, 2013a [87]); (Durham, 2012 [88]); (Martin, 2013b [89]); (Hellard, 2014 [90]) Models developed to estimate the impact of HCV testing and treatment on the burden of hepatitis C at a country level reveal that large decreases in HCV prevalence and incidence are possible as

more persons are successfully treated (Wedemeyer, 2014 [91]) There are also benefits to eradicating HCV infection between couples and among families, and thus eliminating the perception that an individual might be contagious. In addition, mother-to-child transmission of HCV does not occur if the woman is not viremic, providing an additional benefit of curing a woman before she becomes pregnant. (Thomas, 1998 [92]) However, the safety and efficacy of treating women who are already pregnant to prevent transmission to the fetus have not yet been established, and thus treatment is not recommended for pregnant women.

The Society for Healthcare Epidemiology of America (SHEA) advises that health-care workers who have substantial HCV viral replication (≥104 genome equivalents/mL) be restricted from performing procedures that are prone to exposure (Henderson, 2010 [93]) and that all health-care workers with confirmed chronic HCV infection should be treated. For reasons already stated above, the achievement of an SVR in such individuals will not only eliminate the risk of HCV transmission to patients but also decrease circumstantial loss of experienced clinicians. Given concerns about underreporting of infection and transmission (Henderson, 2010 [93]), the availability of effective, all-oral regimens should lead to greater willingness on the part of exposure-prone clinicians to be tested and treated.

Successful treatment of HCV-infected persons at greatest risk for transmission represents a formidable tool to help stop HCV transmission in those who continue to engage in high-risk behaviors. To guide implementation of hepatitis C treatment as a prevention strategy, studies are needed to define the best candidates for treatment to stop transmission, the additional interventions needed to maximize the benefits of HCV treatment (eg, preventing reinfection), and the cost-effectiveness of the strategies when used in target populations.

Persons who inject drugs. Injection drug use (IDU) is the most common risk factor for HCV infection in the United States and Europe, with an HCV seroprevalence of 10% to 70%: (Amon, 2008 [94]); (Nelson, 2011 [95]) IDU also accounts for the majority of new HCV infections (approximately 70%) and is the key driving force in the perpetuation of the epidemic. Given these facts and the absence of an effective vaccine against HCV, testing and linkage to care combined with treatment of HCV infection with potent IFN-free regimens has the potential to dramatically decrease HCV incidence and prevalence. (Martin, 2013b [89]) However, treatment-based strategies to prevent HCV transmission have yet to be studied, including how to integrate hepatitis C treatment with other risk-reduction strategies (eg, opiate substitution therapy, needle and syringe exchange programs). (Martin, 2013a [87])

In studies of IFN-containing treatments in persons who inject drugs, adherence and efficacy rates are comparable to those of patients who do not use injection drugs. A recent meta-analysis of treatment with PEG-IFN with or without RBV in active or recent injection drug users showed SVR rates of 37% and 67% for HCV genotype 1 or 4 and 2 or 3, respectively. (Aspinall, 2013 [96]) As shorter, better-tolerated, and more efficacious IFN-free therapies are introduced, these SVR rates are expected to improve. Importantly, the rate of reinfection in this population is lower (2.4/100 person-years of observation) than that of incident infection in the general population of injection drug users (6.1-27.2/100 person-years), although reinfection increases with active or ongoing IDU (6.44/100 person-years) and available data on follow-up duration are limited. (Aspinall, 2013 [96]); (Grady, 2013 [97])

Ideally, treatment of HCV-infected persons who inject drugs should be delivered in a multidisciplinary care setting with services to reduce the risk of reinfection and for management of the common social and psychiatric comorbidities in this population. Regardless of the treatment setting, recent and active IDU should not be seen as an absolute contraindication to HCV therapy. There is strong evidence from various

settings in which persons who inject drugs have demonstrated adherence to treatment and low rates of reinfection, countering arguments that have been commonly used to limit access to this patient population. (Aspinall, 2013 [96]); (Hellard, 2014 [98]); (Grebely, 2011 [99]) Indeed, combining HCV treatment with needle exchange and opioid agonist therapy programs in this population with a high prevalence of HCV infection has shown great value in decreasing the burden of HCV disease. Elegant modeling studies illustrate the high return on the modest investment of addressing this often-ignored segment of the HCV-infected population. (Martin, 2013a [89]) These conclusions were drawn before the introduction of the latest DAA regimens. Conversely, there are no data to support the utility of pretreatment screening for illicit drug or alcohol use in identifying a population more likely to successfully complete HCV therapy. These requirements should be abandoned, because they create barriers to treatment, add unnecessary cost and effort, and potentially exclude populations that are likely to obtain substantial benefit from therapy. Scale up of HCV treatment in persons who inject drugs is necessary to positively impact the HCV epidemic in the United States and globally.

HIV-infected men who have sex with men (MSM) who engage in high-risk sexual practices. Over the past decade, a dramatic increase in incident HCV infections among HIV-infected MSM who did not report IDU as a risk factor has been demonstrated in several US cities. (van de Laar, 2010 [100]) Recognition and treatment of HCV infection (including acute infection) in this population may represent an important step in preventing subsequent infections. As with persons who inject drugs, HIV/HCV-coinfected MSM who engage in ongoing high-risk sexual practices should be treated for their HCV infection in conjunction with continued education on risk-reduction strategies. In particular, safer-sex strategies should be emphasized given the high rates of reinfection after SVR, which may approach 30% over 2 years, in HIV-infected MSM with acute HCV infection. (Lambers, 2011 [101])

Incarcerated persons. Among incarcerated individuals, the rate of HCV seroprevalence ranges from 30% to 60% (Post, 2013 [102]) and the rate of acute infection is approximately 1%. (Larney, 2013 [103]) Screening for HCV infection is relatively uncommon in state prison systems. Treatment uptake has been limited in part because of the toxic effects and long treatment duration of older IFN-based therapies as well as concerns about cost. (Spaulding, 2006 [104]) In particular, truncation of HCV treatment owing to release from prison has been cited as a major limitation to widespread, effective HCV treatment in correctional facilities. (Post, 2013 [102]), (Chew, 2009 [105]) Shorter (12- to 24-week) HCV therapies reduce duration of stay-related barriers to HCV treatment in prisons. Likewise, the improved safety of newer, all-oral regimens diminishes concerns of toxic effects. Coordinated treatment efforts within prison systems would likely rapidly decrease the prevalence of HCV infection in this at-risk population, although research is needed in this area.

Persons on hemodialysis. The prevalence rate of HCV infection is markedly elevated in persons on hemodialysis and ranged from 2.6% to 22.9% in a large multinational study. (Fissell, 2004 [106]) Studies in the United States found a similarly elevated prevalence rate of 7.8% to 8.9%. (Centers for Disease Control and Prevention, 2001 [107]); (Finelli, 2005 [108]) Importantly, the seroprevalence of HCV was found to increase with time on dialysis, suggesting that nosocomial transmission, among other risk factors, plays a role in HCV acquisition in these patients. (Fissell, 2004 [106]) Improved education and strict adherence to universal precautions can drastically reduce nosocomial HCV transmission risks for persons on hemodialysis. (Hoey, 1996 [109]) but clearance of HCV viremia through treatment-induced SVR eliminates the potential for transmission.

HCV-infected persons on hemodialysis have a decreased quality of life and increased mortality compared with uninfected persons on hemodialysis. (Fabrizi, 2002 [110]); (Fabrizi, 2004 [111]); (Fabrizi, 2009 [112])

HCV infection in this population also has a deleterious impact on kidney transplantation outcomes with decreased patient and graft survival. (Fabrizi, 2014 [113]) The increased risk for nosocomial transmission and the substantial clinical impact of HCV infection in those on hemodialysis are compelling arguments for HCV therapy as effective antiviral regimens that can be used in persons with advanced renal failure become available (see Unique Patient Populations: Patients with Renal Impairment [4])

Populations Unlikely to Benefit From HCV Treatment

Patients with a limited life expectancy that cannot be remediated by treating HCV, by transplantation, or by other directed therapy do not require treatment. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert. Chronic hepatitis C is associated with a wide range of comorbid conditions. (Butt, 2011 [114]); (Louie, 2012 [115]) Little evidence exists to support initiation of HCV treatment in patients with limited life expectancy (less than 12 months) owing to non-liver-related comorbid conditions. For these patients, the benefits of HCV treatment are unlikely to be realized and palliative care strategies should take precedence. (Holmes, 2006 [116]); (Maddison, 2011 [117])

Recommendations for Pretreatment Assessment

- **Evaluation for advanced fibrosis using liver biopsy, imaging, and/or noninvasive markers is recommended for all persons with HCV infection, to facilitate an appropriate decision regarding HCV treatment strategy and to determine the need for initiating additional measures for the management of cirrhosis (eg, hepatocellular carcinoma screening). (see HCV Testing and Linkage to Care [118])**
  Rating: Class I, Level A

An accurate assessment of fibrosis remains vital, as degree of hepatic fibrosis is one of the most robust prognostic factors used to predict HCV disease progression and clinical outcomes. (Everhart, 2010 [119]) Individuals with severe fibrosis require surveillance monitoring for liver cancer, esophageal varices, and hepatic function. (Garcia-Tsao, 2007 [120]); (Brunt, 2011 [121]) In some instances, the recommended duration of treatment is also longer [122].

Although liver biopsy is the diagnostic standard, sampling error and observer variability limit test performance, particularly when inadequate sampling occurs. Up to one-third of bilobar biopsies had a difference of at least 1 stage between the lobes. (Bedossa, 2003 [123]) In addition, the test is invasive and minor complications are common, limiting patient and practitioner acceptance. Serious complications such as bleeding, although rare, are well recognized.

Noninvasive tests to stage the degree of fibrosis in patients with chronic HCV infection include models incorporating indirect serum biomarkers (routine tests), direct serum biomarkers (components of the extracellular matrix produced by activated hepatic stellate cells), and vibration-controlled transient liver elastography. No single method is recognized to have high accuracy alone and each test must be interpreted carefully. A recent publication of the Agency for Healthcare Research and Quality found

Vibration-controlled transient liver elastography is a noninvasive way to measure liver stiffness and correlates well with measurement of substantial fibrosis or cirrhosis in patients with chronic HCV infection. The measurement range does overlap between stages. (Ziol, 2005 [125]), (Afdhal, 2015 [126]); (Castera, 2005 [127])

The most efficient approach to fibrosis assessment is to combine direct biomarkers and vibration-controlled transient liver elastography. (Boursier, 2012 [128]); (European Association for the Study of the Liver and Asociacion Latinoamericana para el Estudio del Higado, 2015 [129]) A biopsy should be considered for any patient who has discordant results between the 2 modalities that would affect clinical decision making. For example, one shows cirrhosis and the other does not. The need for liver biopsy with this approach is markedly reduced.

Alternatively, if direct biomarkers or vibration-controlled transient liver elastography are not available, the AST-to-platelet ratio index (APRI) or FIB-4 index score can help. (Sebastiani, 2009 [130]); (Castera, 2010 [131]); (Chou, 2013b [132]) although neither test is sensitive enough to rule out substantial fibrosis. (Chou, 2013b [132]) Biopsy should be considered in those in whom more accurate fibrosis staging would impact treatment decisions. Individuals with clinically evident cirrhosis do not require additional staging (biopsy or noninvasive assessment).

Recommendations for Repeat Liver Disease Assessment

- **Ongoing assessment of liver disease is recommended for persons in whom therapy is deferred.**
  Rating: Class I, Level C

When therapy is deferred, it is especially important to monitor liver disease in these patients. In line with evidence-driven recommendations for treatment of nearly all HCV-infected patients, several factors must be taken into consideration if treatment deferral is entertained or mandated by lack of medication access. As noted, strong and accumulating evidence argue against deferral because of decreased all-cause morbidity and mortality, prevention of onward transmission, and quality-of-life improvements for patients treated regardless of baseline fibrosis. Additionally, treatment of HCV infection may improve or prevent extraheptatic complications, including diabetes mellitus, cardiovascular disease, renal disease, and B-cell non-Hodgkin lymphoma. (Conjeevaram, 2011 [133]); (Hsu, 2015 [134]); (Torres, 2015 [135]) which are not tied to fibrosis stage. (Allison, 2015 [136]); (Petta, 2015 [137]) Deferral practices based on fibrosis stage alone are inadequate and shortsighted.

Fibrosis progression varies markedly between individuals based on host, environmental, and viral factors (**Table 1** [138]). (Poynard, 2005 [139]) Fibrosis may not progress linearly. Some individuals (often those aged ≥50 years) may progress slowly for many years followed by an acceleration of fibrosis progression. Others may never develop substantial liver fibrosis despite longstanding infection. The presence of existing fibrosis is a strong risk factor for future fibrosis progression. Fibrosis results from chronic hepatic necroinflammation, and thus a higher activity grade on liver biopsy and higher serum transaminase values are associated with more rapid fibrosis progression. (Ghany, 2013 [140]) However, even patients with normal ALT levels may develop substantial liver fibrosis over time. (Prati, 2002 [141]); (Nutt, 2000 [142]) The limitations of transient elastography and liver biopsy in ascertaining the progression of fibrosis must be recognized.

Host factors associated with more rapid fibrosis progression include male sex, longer duration of infection, and older age at the time of infection. (Poynard, 2001 [143]) Many patients have concomitant nonalcoholic fatty liver disease, and the presence of hepatic steatosis with or without steatohepatitis on liver biopsy, elevated body mass index, insulin resistance, and iron overload are associated with fibrosis progression. (Konerman, 2014 [54]); (Everhart, 2009 [144]) Chronic alcohol use is an important risk factor because alcohol consumption has been associated with more rapid fibrosis progression. (Feld, 2006 [139]) A safe amount of alcohol consumption has not been established. Cigarette smoking may also lead to more rapid fibrosis progression. For more counseling recommendations, please see Testing and Linkage to Care [145].

Immunosuppression leads to more rapid fibrosis progression, particularly HIV/HCV coinfection and solid organ transplantation. (Macias, 2009 [53]); (Konerman, 2014 [54]); (Berenguer, 2013 [146]) Therefore, immunocompromised patients should be treated even if they have mild liver fibrosis at presentation.

Level of HCV RNA does not correlate with stage of disease (degree of inflammation or fibrosis). Available data suggest that fibrosis progression occurs most rapidly in patients with HCV genotype 3 infection. (Kanwal, 2014 [147]); (Bochud, 2009 [148]) Aside from coinfection with HBV or HIV, no other viral factors are consistently associated with disease progression.

Although an ideal interval for assessment has not been established, annual evaluation is appropriate to discuss modifiable risk factors and to update testing for hepatic function and markers for disease progression. For all individuals with advanced fibrosis, liver cancer screening dictates a minimum of evaluation every 6 months.

When and in Whom to Initiate HCV Therapy Table 1. Factors Associated With Accelerated Fibrosis Progression

Host	Viral
Nonmodifiable	HCV genotype 3
Fibrosis stage	Coinfection with hepatitis B virus or HIV
Inflammation grade	
Older age at time of infection	
Male sex	
Organ transplant	
Modifiable	
Alcohol consumption	
Nonalcoholic fatty liver disease	
Obesity	
Insulin resistance	

Updated February 24, 2016.

Published on *Recommendations for Testing, Managing, and Treating Hepatitis C* (http://live.hcv.guidance-new.gotpantheon.com)

When and in Whom to Initiate HCV Therapy Box. Summary of Recommendations for When and in Whom to Initiate HCV Therapy

Summary of Recommendations for When and in Whom to Initiate HCV Therapy

Goal of Treatment

- The goal of treatment of HCV-infected persons is to reduce all-cause mortality and liver-related health adverse consequences, including end-stage liver disease and hepatocellular carcinoma, by the achievement of virologic cure as evidenced by a sustained virologic response.
  Rating: Class I, Level A

Recommendations for When and in Whom to Initiate Treatment

- Treatment is recommended for all patients with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. Patients with short life expectancies owing to liver disease should be managed in consultation with an expert.
  Rating: Class I, Level A

Recommendations for Pretreatment Assessment

- Evaluation for advanced fibrosis using liver biopsy, imaging, and/or noninvasive markers is recommended for all persons with HCV infection, to facilitate an appropriate decision regarding HCV treatment strategy and to determine the need for initiating additional measures for the management of cirrhosis (eg, hepatocellular carcinoma screening). (see HCV Testing and Linkage to Care [1])
  Rating: Class I, Level A

Recommendations for Repeat Liver Disease Assessment

- Ongoing assessment of liver disease is recommended for persons in whom therapy is deferred
  Rating: Class I, Level C

When and in Whom to Initiate HCV Therapy Table 1. Factors Associated with Accelerated Fibrosis Progression

Host	Viral
Nonmodifiable	HCV genotype 3
Fibrosis stage	Coinfection with hepatitis B virus or HIV
Inflammation grade	
Older age at time of infection	
Male sex	
Organ transplant	
Modifiable	
Alcohol consumption	
Nonalcoholic fatty liver disease	
Obesity	
Insulin resistance	

Updated February 24, 2016

Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection

Federal Bureau of Prisons
Clinical Practice Guidelines

July 2015

Clinical guidelines are made available to the public for informational purposes only. The Federal Bureau of Prisons (BOP) does not warrant these guidelines for any other purpose, and assumes no responsibility for any injury or damage resulting from the reliance thereof. Proper medical practice necessitates that all cases are evaluated on an individual basis and that treatment decisions are patient-specific. Consult the FBOP *Health Management Resources* Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mngmt.jsp .

What's New in BOP Guidance Regarding HCV Infection?

These June 2015 guidelines replace both of the following guidelines issued by the Federal Bureau of Prisons (BOP) in 2014:

- *Treatment of Hepatitis C with Pegylated Interferon and Ribavirin, with or without Boceprevir or Telaprevir*
- *Interim Guidance for the Management of Chronic Hepatitis C Infection*

A new era in the treatment of HCV infection began in 2013 and 2014, with the approval of new direct-acting antiviral (DAA) oral medications that act directly against HCV without the use of interferon. These newer regimens are very effective in eliminating HCV infection, achieving cure rates of greater than 90% in many patient populations. In addition, the availability of interferon-free regimens has expanded treatment elibility to include groups for whom treatment had been contraindicated, e.g., decompensated cirrhosis. The preferred treatment regimens have changed as each new DAA has been approved—resulting in rapidly changing clinical guidelines and treatment recommendations. In the midst of this evolving treatment landscape, the most recently published guidance on HCV treatment stresses the importance of referring regularly to the AASLD/IDSA/IAS-USA website (www.hcvguidelines.org) for new updates.

> ***Note:*** *The HCV website is provided by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA, in collaboration with the International Antiviral Society–USA (IAS–USA). See the* References *section for a complete citation.*

The AASLD/IDSA/IAS-USA guidelines also indicate that it is reasonable during this time of transition to prioritize for treatment those HCV cases with the most urgent need. These June 2015 guidelines describe the current treatment priorities established by the BOP, as well as the current medication regimens recommended for the treatment of HCV. The BOP Central Office Medical staff will continue to monitor the AASLD/IDSA/IAS-USA website and provide revised guidance as necessary.

Table of Contents

1. Purpose and Overview

The Federal Bureau of Prisons (BOP) Clinical Practice Guidelines on *Evaluation and Management of Chronic Hepatitis C Virus (HCV) Infection* provide the most current BOP guidance for the treatment of chronic HCV infection in the federal inmate population.

In light of the rapidly changing HCV treatment landscape, the BOP Central Office Medical staff will continue to monitor the AASLD/IDSA/IAS-USA website (www.hcvguidelines.org) and provide revised guidance as necessary. Be sure to consult the BOP *Health Management Resources* Web page to determine the date of the most recent update to this document: http://www.bop.gov/resources/health_care_mgmt.jsp .

> ***Note:*** *The HCV website is provided by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA), in collaboration with the International Antiviral Society–USA (IAS–USA). See the* Reference *section for a complete citation.*

2. Screening for HCV Infection

Inmate History and Patient Education

A health history should be obtained from all newly incarcerated BOP inmates. In addition, these inmates should be provided with educational information regarding prevention and transmission, risk factors, testing, and medical management of HCV infection, in accordance with BOP policy. Health education efforts should make use of the BOP peer-oriented video on infectious diseases, *Staying Alive*, located in Section 5: A–Z Topics on the HSD Infection Control Website, http://sallyport.bop.gov/cn-hsd/infectious_disease/index.jsp .

Screening Criteria

Testing for HCV infection is recommended (**a**) for *sentenced* inmates with risk factors for HCV infection, (**b**) for *all* inmates with certain clinical conditions, and (**c**) for inmates who request testing.

a. Risk Factors: Testing for HCV infection at the prevention baseline visit is recommended for *sentenced* inmates who have the following risk factors:

- Ever injected illegal drugs or shared equipment (including intranasal use of illicit drugs)
- Received tattoos or body piercings while in jail or prison, or from any unregulated source
- HIV or chronic hepatitis B virus (HBV) infection
- Received a blood transfusion or an organ transplant before 1992, or received clotting factor transfusion prior to 1987
- History of percutaneous exposure to blood
- Ever received hemodialysis
- Born to a mother who had HCV infection at the time of delivery

b. Clinical Conditions: HCV testing is recommended for *all* inmates with the following clinical conditions, *regardless of sentencing status*:

- A reported history of HCV infection without prior medical records to confirm the diagnosis
- Chronic hemodialysis – screen alanine aminotransferase (ALT) monthly and anti-HCV semiannually
- Elevated ALT levels of unknown etiology
- Evidence of extrahepatic manifestations of HCV – mixed cryoglobulinemia, membranoproliferative glomerulonephritis, porphyria cutanea tarda, vasculitis

Screening Method

The preferred screening test for HCV infection is an immunoassay that measures the presence of antibodies to HCV antigens, referred to as *HCV Ab* or *anti-HCV*.

Screening of Nonsentenced Inmates

Unless clinically indicated (see *clinical conditions* under Screening Criteria above), screening should ordinarily not be pursued for asymptomatic, highly mobile, nonsentenced inmates. Referrals to community HCV testing sites should be made when appropriate.

Exception: *Long-term inmates in BOP detention facilities should be screened for HCV infection in accordance with the guidelines for sentenced inmates.*

Refusal of Testing

Sentenced inmates who have risk factors for HCV infection, but who refuse testing at the baseline visit, should be counseled about and offered HCV testing during periodic preventive health visits.

3. Initial Evaluation of Anti-HCV Positive Inmates

Initial evaluation of anti-HCV positive inmates includes **(a)** a baseline history and physical examination, **(b)** lab tests, and **(c)** calculation of the APRI score to determine fibrosis. The inmate should also be evaluated to assess the need for **(d)** preventive health interventions such as vaccines and screenings for other conditions, as well as counseled with **(e)** information on HCV infection.

➔ *Determining whether the patient meets BOP criteria for priority treatment is an important part of the initial evaluation of anti-HCV positive inmates. If cirrhosis is present, see Section 4. Assess for Hepatic Cirrhosis and Decompensation, to determine whether the liver disease is compensated or decompensated. Section 5. BOP Priority Criteria for Treatment, lists the clinical scenarios that will be used in the BOP to prioritize inmates for treatment.*

Baseline Evaluation

A baseline clinician evaluation should be conducted for all inmates who are anti-HCV positive. At minimum, this evaluation should include the following:

a. Targeted history and physical examination:

- Evaluate for signs and symptoms of liver disease, quantify prior alcohol consumption, and determine risk behaviors for acquiring HCV infection (see section on *Risk Factors* under Screening Criteria above). Attempt to estimate the earliest possible date of infection, including when risk factors for exposures started and stopped, e.g., the time period in which the inmate engaged in injection drug use.
- Evaluate for other possible causes of liver disease, especially alcoholism, nonalcoholic steatohepatitis (NASH), iron overload, and autoimmune hepatitis.
- Inquire about prior treatment for HCV infection, specific medications used, dosages and duration of treatment, and outcomes, if known.

b. Laboratory tests:

Recommended baseline laboratory tests are listed in Appendix B and include the following:

- Complete blood count (CBC); prothrombin time (PT) with International Normalization Ratio (INR); liver panel (albumin, total and direct bilirubin, serum alanine aminotransferase [ALT] and aspartate aminotransferase [AST], and alkaline phosphatase); serum creatinine; and calculated glomerular filtration rate (GFR).
  - ➔ *Unexplained abnormalities should prompt additional diagnostic evaluations, as clinically indicated, to determine the underlying cause, e.g., low hemoglobin/platelet count or GFR.*
- Hepatitis B surface antigen (HBsAg) and HIV antibody (anti-HIV or HIV Ab).
  - ➔ *Refer to the respective BOP Clincal Practice Guidelines for management of a positive HBsAg or HIV Ab test.*
- Quantitative HCV RNA viral load testing to determine if the inmate has active or resolved HCV infection.
  - ➔ *Ordinarily, testing for HCV genotype may be deferred until the time of pretreatment evaluation.*
- Unless otherwise clinically indicated, testing for other causes of liver disease—e.g., antinuclear antibody (ANA), ferritin, iron saturation, ceruloplasmin—are not routinely ordered in the evaluation of a positive HCV Ab test.

c. Calculation of the AST (aspartate aminotransferase) to Platelet Ratio Index (APRI) to assess the degree of fibrosis:

- The APRI score, a calculation based on results from two blood tests (the AST and the platelet count), is a less invasive and less expensive means of assessing fibrosis than a liver biopsy.

- The formula for calculating the APRI score is [(AST/AST ULN) x 100 / (platelet count x 10^3/µL / 1,000). A calculator is available at:

  http://www.hepatitisc.uw.edu/page/clinical-calculators/apri

- If a person is known to have cirrhosis, the APRI is irrelevant and unnecessary.

d. Preventive health measures:

All inmates who are anti-HCV positive should be evaluated to assess the need for the preventive health interventions, including the following:

- **Hepatitis B vaccine:** Indicated for susceptible inmates with chronic HCV infection. For foreign-born inmates, consider prescreening for hepatitis B immunity prior to vaccination.
  - ➔ *Inmates with evidence of liver disease should be priority candidates for hepatitis B vaccination.*
- **Hepatitis A vaccine:** Indicated for susceptible inmates with chronic HCV infection who have other evidence of liver disease. For foreign-born inmates, consider prescreening for hepatitis A immunity prior to vaccination.
- **Influenza vaccine:** Offer to all HCV-infected inmates annually.
  - ➔ *Inmates with cirrhosis are high priority for influenza vaccine.*

e. Patient Education:

Inmates diagnosed with chronic HCV infection should be counseled by a health care provider regarding the natural history of the infection, potential treatment options, and specific measures to prevent transmitting HCV infection to others (both during incarceration and upon release).

4. Assess for Hepatic Cirrhosis and Decompensation

Cirrhosis is a condition of chronic liver disease marked by inflammation, degeneration of hepatocytes, and replacement with fibrotic scar tissue. The natural history of HCV is such that 50–80% of HCV infections become chronic. Progression of chronic HCV infection to fibrosis and cirrhosis may take years in some patients and decades in others—or, in some cases, may not occur at all. Most complications from HCV infection occur in people with cirrhosis.

- Patients with advanced hepatic fibrosis (primarily stage 3) have a 10% per year rate of progressing to cirrhosis (stage 4).
- Those with cirrhosis have a 4% per year rate of developing decompensated cirrhosis, and a 3% per year rate of developing hepatocellular carcinoma.

➔ *The Child-Turcotte-Pugh (CTP) score is a useful tool in determining the severity of cirrhosis and in distinguishing between compensated and decompensated liver disease. See the discussion below under "Assessing Hepatic Decompensation".*

Assessing for Hepatic Cirrhosis

Assessing for cirrhosis is important for prioritizing inmates for treatment of HCV and in determining the need for additional health care interventions. Cirrhosis may be diagnosed in several ways:

- **Symptoms and signs that support the diagnosis of cirrhosis may include:** low albumin or platelets, elevated bilirubin or INR, ascites, esophageal varices, and hepatic encephalopathy. However, isolated lab abnormalities may require additional diagnostic evaluation to determine the etiology.

- **The APRI score is the BOP-preferred method for non-invasive assessment of hepatic fibrosis and cirrhosis:**
  - ***An APRI score ≥ 2.0 may be used to predict the presence of cirrhosis.*** At this cutoff, the APRI score has a sensitivity of 48%, but a specificity of 94%, for predicting cirrhosis. Inmates with an APRI score ≥ 2.0 should have an abdominal ultrasound performed to identify other findings consistent with cirrhosis (see abdominal imaging studies below in this list). Lower APRI scores have different sensitivities and specificities for cirrhosis. For example, an APRI score ≥ 1 has a sensitivity of 77% and a specificity of 75% for predicting cirrhosis.
    - ➔ *An APRI score is not necessary for diagnosing cirrhosis if cirrhosis has been diagnosed by other means.*
  - ***The APRI may also be used to predict the presence of significant fibrosis (stages 2 to 4, out of 4).*** Using a cutoff of ≥ 1.5, the sensitivity is 37% and specificity is 95% for significant fibrosis.

- **Liver biopsy** is no longer required unless otherwise clinically indicated. However, the presence of cirrhosis on a prior liver biopsy may be used to meet the BOP criteria for HCV treatment.

- **Abdominal imaging studies** such as ultrasound or CT scan may identify findings consistent with or suggestive of ***cirrhosis*** (nodular contour of the liver), ***portal hypertension*** (ascites, splenomegaly, varices), or ***hepatocellular carcinoma*** (HCC).

Assessing Hepatic Compensation

Assessing hepatic compensation is important for determining the most appropriate HCV treatment regimen to be used. The recommended HCV treatment regimen may differ depending on whether the cirrhosis is compensated or decompensated.

The CTP score is a useful tool to help determine the severity of cirrhosis and is used by the AASLD to distinguish between compensated and decompensated liver disease.

➔ *CTP calculators are readily available on the Internet and are not reproduced in these guidelines:* http://www.hepatitis.va.gov/cpg/clinical-calculators.asp

The CTP score includes five parameters (albumin, bilirubin, INR, ascites, and hepatic encephalopathy), each of which is given a score of 1, 2, or 3. The sum of the five scores is the CTP score, which is classified as shown in the table below:

CTP Score	CTP Class	Hepatic Compensation
5–6	Class A	Compensated cirrhosis
7–9	Class B	Decompensated cirrhosis
≥ 10	Class C	

A CTP score of 5 or 6 is considered to be *compensated* cirrhosis, while a score of 7 or greater is considered *decompensated.*

→ *It is recommended that cases of decompensated cirrhosis be managed in consultation with a clinician experienced in the treatment of this condition because the dosages of DAA medications are not well-established with severe hepatic impairment.*

→ *Inmates with CTP Class C decompensated cirrhosis may have a reduced life expectancy and should be considered for Reduction In Sentence/Compassionate Release in accordance with current policy (PS 5050.49) and procedures.*

Additional Interventions for Inmates with Cirrhosis:

- **Pneumococcal vaccine:** Offer to all HCV-infected inmates with cirrhosis who are 19 through 64 years of age
  → *See the BOP Clinical Practice Guidelines on Preventive Health Care.*
- **Hepatocellular carcinoma (HCC) screening:** Liver ultrasound is recommended every six months for patients with both cirrhosis *and* chronic HCV infection.
- **Esophageal varices screening:** Screening for esophageal and gastric varices with esophagogastroduodenoscopy (EGD) is recommended for patients diagnosed with cirrhosis.

Other healthcare interventions recommended for patients with cirrhosis may include:

- Nonselective beta blockers for prevention of variceal bleeding in patients with esophageal varices.
- Antibiotic prophylaxis if risk factors are present for spontaneous bacterial peritonitis.
- Optimized diuretic therapy for ascites.
- Lactulose and rifaximin therapy for encephalopathy.

In general, NSAIDs should be avoided in advanced liver disease/cirrhosis, and metformin should be avoided in decompensated cirrhosis. The detailed management of cirrhosis is beyond the scope of these guidelines. Other resources should be consulted for more specific recommendations related to this condition.

5. BOP Priority Criteria for HCV Treatment

Determining whether BOP priority criteria for treatment are met is an important part of the initial evaluation and ongoing management of inmates with chronic HCV infection. Although all patients with chronic HCV infection may benefit from treatment, certain cases are at higher risk for complications or disease progression and require more urgent consideration for treatment. The BOP has established priority criteria to ensure that those with the greatest need are identified and treated first. The BOP Medical Director will provide periodic guidance on specific strategies for implementing these priority levels.

Priority Level 1 – Highest Priority for Treatment*

- **Cirrhosis**
  - This includes cases of known cirrhosis or clinical findings consistent with cirrhosis.
    - → *Cases of decompensated cirrhosis with a CTP score of 7 to 9 should receive the highest priority for treatment.*
  - Patients with an isolated APRI score ≥ 2 with no other clinical findings of cirrhosis are included in Priority Level 2.
- **Liver transplant candidates or recipients**
  - Other types of transplant candidates or recipients may be appropriate to prioritize for treatment and will be considered individually on a case-by-case basis.
- **Hepatocellular carcinoma (HCC)**
  - At least one third of all cases of HCC occur in association with HCV infection, with most cases occurring in those with advanced fibrosis or cirrhosis.
  - Current guidelines do not address the role of HCV treatment in the management of HCC.
  - HCV treatment in HCC cases will be determined individually and require consultation with an appropriate specialist.
- **Comorbid medical conditions associated with HCV, including:**
  - Cryoglobulinemia with renal disease or vasculitis.
  - Certain types of lymphomas or hematologic malignancies.
- **Immunosuppressant medication for a comorbid medical condition**
  - Some immusuppressant medications (e.g., certain chemotherapy agents and tumor necrosis factor inhibitors) may be needed to treat a comorbid medical condition, but are not recommended for use when infection is present. However, data are insufficient and current guidelines are inconsistent regarding treatment of HCV infection in this setting. Such cases will be considered for HCV treatment on an individual basis.
- **Continuity of care for those already started on treatment**, including inmates who are newly incarcerated in the BOP.

Priority Level 2 – High Priority for Treatment*

- APRI score ≥ 2
- Advanced fibrosis on liver biopsy (e.g., Metavir Stage 3 bridging fibrosis)
- HBV coinfection
- HIV coinfection
- Comorbid liver diseases (e.g., autoimmune hepatitis, hemochromatosis, steatohepatitis, etc.)

Priority Level 3 – Intermediate Priority for Treatment*

- Stage 2 fibrosis on liver biopsy
- APRI score 1.5 to < 2
- Diabetes mellitus
- Porphyria cutanea tarda

Priority Level 4 – Routine Priority for Treatment*

- Stage 0 to stage 1 fibrosis on liver biopsy
- All other cases of HCV infection meeting the eligibility critera for treatment, as noted below under *Other Criteria for Treatment*

* ***Exceptions to the above criteria for Priority Levels 1–4 will be made on an individual basis and will be determined primarily by a compelling or urgent need for treatment, such as evidence for rapid progression of fibrosis, or deteriorating health status from other comorbidities.***

Other Criteria for Treatment

In addition to meeting the above criteria for Priority Levels 1–4, inmates being considered for treatment of HCV infection should:

- Have no contraindications to, or signicifant drug interactions with, any component of the treatment regimen.
- Have a GFR ≥ 30.
- Not be pregnant, especially for any regimen that would require ribavirin or interferon.
- Have sufficient time remaining on their sentence in the BOP to complete a course of treatment.
- Have a life expectancy > 18 months.
- Demonstrate a willingness and an ability to adhere to a rigorous treatment regimen and to abstain from high-risk activities while incarcerated.

6. Recommended Treatment Regimens

Recommendations for preferred HCV treatment regimens continue to evolve, but still depend on several factors:

- HCV genotype
- Prior HCV treatment history
- Compensated vs. decompensated liver disease

Direct Acting Antiviral Medications (DAAs)

As the name implies, these antiviral medications for HCV infection act directly on some part of the virus, usually the replication mechanism. Currently, there are three classes of HCV DAAs: polymerase inhibitors (-buvir), protease inhibitors (-previr), and NS5A replication complex inhibitors (-asvir). DAAs cannot be used as monotherapy; they must be used in combination with at least one other DAA or with ribavirin, depending on the clinical scenario.

The most commonly recommended regimens are briefly described below. More detailed information about these regimens and the individual medications—including indications, contraindications, dosing and duration, and drug interactions—may be found in the appendices.

- **Ledipasvir/sofosbuvir (Harvoni®)**
  - A coformulation of 90 mg of ledipasvir and 400 mg of sofosbuvir, taken once daily for 12 or 24 weeks.
  - FDA-approved for treatment of HCV genotype 1, alone or in combination with ribavirin.
  - AASLD also recommends this as an option for treatment of HCV genotype 4, 5, or 6.
- **Paritapravir/ritonavir/ombitasvir + dasabuvir (Viekira Pak™)**
  - Includes two tablets, each coformulated with 12.5 mg of ombitasvir, 75 mg of paritaprevir, and 50 mg of ritonavir, in addition to two 250 mg tablets of dasabuvir.
  - FDA-approved for treatment of HCV genotype 1, alone or in combination with ribavirin.
  - AASLD also recommends this as an option for treatment of HCV genotype 4, and for certain cases of genotype 1 or 4 with chronic kidney disease and GFR <30 for whom urgent HCV treatment is needed.
  - Not approved for use with decompensated cirrhosis.
- **Sofosbuvir + simeprevir**
  - Taken together once daily, 400 mg of sofosbuvir and 150 mg of simeprevir.
  - FDA-approved for treatment of HCV genotype 1.
  - When used for the treatment of genotype 1a, a test for HCV virologic resistance looking for the Q80K polymorphism must be obtained prior to treatment.
- **Sofosbuvir + ribavirin**
  - Taken as 400 mg of sofosbuvir once daily and weight-based ribavirin twice daily.
  - FDA-approved for HCV genotypes 1, 2, or 3, and for genotypes 1 or 4 in combination with weekly pegylated interferon injections.

Preferred Treatment Regimens

The preferred treatment regimens currently recommended by AASLD/IDSA/IAS-USA are included in these BOP guidelines in the following appendices:

- *Appendix 1: Treatment Recommendations for HCV with Cirrhosis*
- *Appendix 2: Treatment Recommendations for HCV with No Cirrhosis*

➔ ***Please refer to the AASLD/IDSA/IAS-USA website (www.hcvguidelines.org) for any updates since June 29, 2015.***